Medical Facilities Planning Section
Draft Summary
PETITIONS and COMMENTS - SUMMER 2007
TECHNOLOGY AND EQUIPMENT

PETITIONS

Linear Accelerators

PETITIONS

1) Moses Cone Health System

Requests an adjusted need determination in Linear Accelerator Service Area 12 (Guilford & Rockingham) to add one (1) linear accelerator with stereotactic radiosurgery capabilities

COMMENTS

Jim Whiting – support need determination for a linear accelerator with stereotactic radiosurgery capability for Moses Cone Health System

Dr. Henry Pool Letter of support - Moses Cone linac

2) Cape Fear Valley Health System

Requests an adjusted need determination for CyberKnife Stereotactic Radiosurgery in Service Area 18

COMMENTS received separate from the Cape Fear's petition itself

Dr. John Henley, Jr. - Letter of support - Cape Fear Valley Health System cyber knife

N.C. Senator Tony Rand – Letter of support - Cape Fear Valley Health System cyber knife

David J. Masterson - Letter of support Cape Fear Valley Health System cyber knife

John G. Buie, Jr. - Letter of support – Cape Fear Valley Health System cyber knife

Former N.C. Rep. Bill Hurley - Letter of support – Cape Fear Valley Health System cyber knife

U.S. Rep. Robin Hayes - Letter of support – Cape Fear Valley Health System cyber knife

Harold L. Godwin, M.D. - Letter of support – Cape Fear Valley Health System cyber knife

James D. Devane - Letter of support Cape Fear Valley Health System cyber knife

Mary Buie, R.N. - Letter of support – Cape Fear Valley Health System cyber knife

Mary G. Buie, R.N. - Letter of support – Cape Fear Valley Health System cyber knife

Richard L. Player - Letter of support – Cape Fear Valley Health System cyber knife

3) Rex Hospital

Requests an adjustment to the inventory of linear accelerators shown on pages 109 and 111 of the Proposed 2008 SMFP to correct the omission of the Franklin Regional Cancer Center

PET Scanners

PETITIONS

The Presbyterian Hospital

Proposes an adjustment to the need methodology in the Proposed 2008 SMFP, Table 9M, pg. 122, to show a need determination for a fixed dedicated positron emission tomography (PET) scanner in Health Service Area (HSA) III

COMMENTS related to the PET Scanner petition for The Presbyterian Hospital

Wallace C. Hollowell Attorney - Comment – Presbyterian Hospital - Support PET scanner need determination in Proposed 2008 SMFP in HSA III

Dr. Robert Quarles - Comment Nuclear Medicine and PET Medical Director - Presbyterian Hospital - PET scanner

Wendy Burkart - Comment – Director of Radiology Services - Presbyterian Hospital PET scanner

Cindi Gilbert - Comment Supervisor of PET Services - Presbyterian Hospital - PET scanner

Dr. L. Scott McGinnis - Comment Radiation Therapy Medical Director - Presbyterian Hospital - PET scanner

COMMENTS related to the Need Determination in HSA II in the Proposed 2008 SMFP

Gregory J. Beier - Noah Huffstetler III – Forsyth Medical Center - support the need methodology in the Proposed 2008 SMFP, Table 9M, pg. 122, which shows a need determination for a fixed dedicated positron emission tomography (PET) scanner in Health Service Area (HSA) II.

Wallace C. Hollowell Comment Forsyth Medical Center - Support PET scanner need determination in Proposed 2008 SMFP in HSA II

Dr. Vito Basile - Comment – Medical Director of Radiology - Forsyth Medical Center – PET scanner

Carmine Plott, Ph.D. - Comment – Radiation Safety Officer Forsyth Medical Center - PET scanner

Devi Mecum - Comment – Radiology Clinical Manager - Forsyth Medical Center - PET s canner

Sharon Murphy - Comment – Executive Director, Regional Cancer Center - Forsyth Medical Center - PET scanner

MRIs

PETITIONS

1) Alliance Imaging Inc.

Petitions for a change in Chapter 9 of the Proposed 2008 SMFP to include the following statement:

"There is no need for any additional mobile magnetic resonance imaging scanners anywhere in the State."

2) Ashe Memorial Hospital

Petitions for an adjusted need determination for one (1) fixed MRI scanner For Ashe County

COMMENTS

R.D. Williams, CEO Ashe Memorial Hospital – In support of adjusted need determination for one fixed MRI scanner in Ashe County

3) Greensboro Orthopaedics, P.A.

Petitions for an adjusted need determination for one (1) MRI Scanner For Guilford County

COMMENTS

David Meyer – In support of adjusted need determination for one fixed MRI scanner in Guilford County

4) HOPE, A Women's Cancer Center

Petitions for an adjusted need determination for one (1) dedicated breast MRI scanner for HSA I

COMMENTS

Mariann Smith – In support of dedicated breast MRI scanner in Buncombe County to serve residents in HSA I.

Upright MRI COMMENTS

Mike Vicario - Comments - Upright MRI

Ruben Fernandez Comments - Upright MRI

F. Del Murphy, Jr - Comment – Multi-Position MRI

Charles Wilson In support of the need determination published in the Proposed 2008 SMFP for four (4) multi-position MRI Scanners to be located in Western and Eastern N.C.

Mark Jensen – Comments - Upright MRI

Dr. Mark Ragozzino – Comments - Upright MRI

Bruce Elder - MedQuest - Comments Upright MRI

Michael Freeman - Comments – Wake Forest University Upright MRI

Dr. David C. Clark against the upright MRI petition

Dr. Robert E. Schaaf - against the upright MRI petition

Dr. Jim Montgomery - Opposes the need determination published in the Proposed 2008 SMFP for four (4) multi-position MRI Scanners to be located in Western and Eastern N.C.

Dr. Michael McLaughlin - Opposes the need determination published in the Proposed 2008 SMFP for four (4) multi-position MRI Scanners to be located in Western and Eastern N.C.

OTHER MRI COMMENTS

Peter W. Acker MRI Need Determination in Lincoln County

David French - Clarification correspondence – Park Ridge Hospital

Cardiac Cath

PETITIONS

1) **Halifax Regional Medical Center**

Requests an adjusted need determination for shared fixed cardiac catheterization equipment in Halifax County

COMMENTS

Supplemental Information for Petitions filed by Halifax Regional Medical Center and Scotland Memorial Hospital for Special Need Determination for Shared Fixed Cardiac Catheterization Laboratories in Halifax and Scotland Counties

William Mahone - - in support of an angiography suite and cardiac catheterization lab at Halifax Regional

Diane Barlow - - in support of an angiography suite and cardiac catheterization lab at Halifax Regional.

Karen Daniels - in support of an angiography suite and cardiac catheterization lab at Halifax Regional.

Michael Joyner -- in support of an angiography suite and cardiac catheterization lab at Halifax Regional.

2) Scotland Memorial

Requests an adjusted need determination for shared fixed cardiac catheterization equipment in Scotland County.

COMMENTS

Supplemental Information for Petitions filed by Halifax Regional Medical Center and Scotland Memorial Hospital for Special Need Determination for Shared Fixed Cardiac Catheterization Laboratories in Halifax and Scotland Counties

Gregory C. Wood - support of Scotland County for a fixed cardiac catheterization lab

Ruth Glaser support of Scotland County for a fixed cardiac catheterization lab

8-16-07 4:30 p.m.

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Technology and Equipment Committee Meeting

August 29, 2007

Radiation Oncology Services - Linear Accelerators Material

Top of Document

Technology and Equipment Committee Meeting

August 29, 2007

Radiation Oncology Services - Linear Accelerators

Material Related To

Linac Petition-1: Moses Cone Health System

MOSES CONE HEALTH SYSTEM

Petition for Adjusted Need Determination
Proposed 2008 State Medical Facilities Plan
Addition of Need for a Linear Accelerator with Stereotactic Radiosurgery
Capabilities in Linear Accelerator Service Area 12

Moses Cone Health System (MCHS) submits this petition to the State Health Coordinating Council (SHCC) requesting an adjusted need determination in Linear Accelerator Service Area 12 (Guilford and Rockingham Counties) to add need for one (1) new piece of linear accelerator equipment with stereotactic radiosurgery (SRS) capabilities.

Background

Stereotactic radiosurgery is an advanced form of radiation therapy that combines stereotactic (three dimensional) localization with multiple cross-fired beams from a collimated radiation source from outside the body. This technology allows delivery of a high dose of radiation to a treatment site while keeping the exposure of healthy tissue at a safe level.[1] As a result, larger and more effective doses of radiation can be administered in fewer treatment sessions to a more precise location. SRS can be used to treat tumors that cannot be treated with traditional radiation therapy or surgical techniques because of their location, number, size, shape or proximity to vital tissues or organs, or because of the age or health of the patient.

As will be discussed subsequently, SRS is establishing a unique role as a highly effective therapy for a growing number of tumor sites. Despite this role, the Certificate of Need Section has determined that SRS is a form of linear accelerator equipment, and this petition is submitted in the context of this determination.

[1] Image-Guided Radiosurgery in the Treatment of Spinal Metastases, Murphy, at al. Neurosurgical Focus. 2001 Dec 15; 11(6):e6.

Rationale for Adjusted Need Request

An adjusted need determination for an SRS-capable linear accelerator is essential to providing state-of-the-art care to the patient population of Linear Accelerator Service Area 12 that currently lacks access to this technology within the defined service area, has a sufficient patient population base to support SRS (greater than 500,000 residents), yet cannot currently acquire SRS technology without negatively affecting existing capacity for established radiation therapy services. The following discussion presents the rationale for approving the requested adjusted need determination.

Clinical Applications

Stereotactic radiosurgery clinical applications are both proven and expanding. SRS technology has been used for more than 30 years, and over 100,000 patients have been treated worldwide. In its earliest form, SRS was used to treat only intracranial (head and neck) tumors or lesions via a Gamma Knife. This system, however, utilizes a rigid metal frame that is fixed to the patient's skull, immobilizing the head so that damage to the healthy tissue surrounding the tumor is minimized when the radiation is delivered. Advancements in technology that can provide SRS via a linear accelerator now enable the delivery of high doses of radiation to intracranial tumors without a metal head frame or to extracranial tumors, such as spine, lung, prostate, liver, and pancreas, while maintaining and even improving submillimeter accuracy to target the tumor or lesion.

Linear accelerators with SRS capabilities are manufactured by Elekta, Novalis, Accuray, Tomotherapy and Varian. This petition does not attempt to highlight one manufacturer over another; rather, this petition seeks to add SRS capabilities to the complement of radiation therapy services provided to residents of Linear Accelerator Service Area 12 without diminishing existing capabilities for traditional radiation therapy.

SRS is one of the fastest-growing areas of oncologic radiation therapy. Sg2, a health care intelligence firm, forecasts that SRS for the treatment of intracranial cancer will grow 108% over the next ten (10) years and SRS for extracranial cancer treatment will grow an astonishing 255% over the next ten (10) years. Intracranial utilization of SRS will increase as the technology is used for patients with multiple or recurrent brain lesions once thought to be untreatable, as clinical efficacy improves for non-cancer indications, such as functional disorders and acoustic neuromas, as incidence of brain metastases increases due to improved survival rates for other primary cancers, and as public awareness and interest in receiving state-of-the-art care increases. Additional factors affecting an increase in utilization of SRS for extracranial applications include growing clinical efficacy of extracranial applications and non-cancer indications, such as benign tumors, increased cancer incidence as a result of an aging population and treatment advances that extend patient longevity, and increasing public awareness and interest in receiving state-of-the-art care.[2]

Physician support for the addition of SRS equipment in Service Area 12 is well established; this support underscores the need for the proposed adjusted need determination. Because SRS is capable of treating both intra- and extracranial tumors, neurosurgeons, oncologists, and radiation oncologists all support the need for availability of SRS for a variety of clinical applications, as evidenced by support letters presented in Exhibit I.

Geographic Access

Current access to intra and extracranial SRS technology for patients living in Service Area 12 is limited. Table 1 lists the current providers of stereotactic radiosurgery in North Carolina and the associated SRS technology.

[2] Sg2 Clinical Intelligence. Stereotactic Radiosurgery: Strategies for Success. 2006.

Table 1
Current North Carolina SRS Providers

Hospital/Facility and City	SRS-Capable Equipment	Intra/Extracranial Capability	Number of Procedures FY 2006
NC Baptist Hospital, Winston-Salem	Gamma Knife, SRS Linac	Intracranial Only, Intra and Extracranial	Gamma knife - 285 SRS - 24
Carolinas Medical Center – Northeast, Concord	Cyberknife	Intra and Extracranial	Not operational in FY 2006
Carolinas Medical Center, Charlotte	Novalis SRS Linac	Intra and Extracranial	95
UNC Hospitals, Chapel Hill	SRS Linac	Intra and Extracranial	62
Duke University Hospital, Durham	Varian SRS Linac and Xknife	Intra and Extracranial	115
Memorial Mission Hospital, Asheville	Cyberknife	Intra and Extracranial	272
Pitt County Memorial Hospital/Brody School of Medicine, Greenville	Gamma Knife and CON application pending for Cyberknife to replace existing SRS-capable unit	Intracranial only for Gamma Knife, Intra and extracranial for SRS Linac	Gamma Knife – 105 SRS – 0
Carolina Radiation Medicine, Greenville	Varian SRS Linac	Intra and extracranial	24

Source: Proposed 2008 State Medical Facilities Plan, facility websites, and "Robot Performs Cancer Surgery", News and Observer, July 2, 2007. newsobserver.com.

Exhibit II presents a map depicting the location of these established SRS providers in North Carolina. Several regions within the state experience excessive distances and travel times for stereotactic radiosurgery, often leading to greater hardships on patients and their families and/or the limitation of referral opportunities. This situation is particularly true in Service Area 12, where the size of the resident population warrants more immediate access to SRS technology.

Additionally, existing or planned stereotactic radiosurgery programs have been developed to serve their established service area populations only; they do not include service to other areas with a sufficient population experiencing high utilization of one or more established linear accelerator providers, i.e. Service

Area 12. Hence, these programs are not positioned to meet the significant demand for SRS treatments from the Service Area 12 resident population.

Current SMFP Linear Accelerator Need Methodology

The current methodology used in the SMFP to determine need for additional linear accelerators does not account for the unique technological aspects of SRS. Although the technology is delivered via an SRS-capable linear accelerator, radiosurgery is a longer procedure than traditional radiation therapy. Average treatment time is 140 minutes in duration depending on tumor location and complexity of treatment plan. The treatment plan will require from one to five fractions or treatments to complete the plan. Therefore, the traditional criterion for evaluating radiation therapy capacity, 6,500 Equivalent Simple Treatment Visits (ESTVs) per linear accelerator annually, does not accurately reflect the utilization patterns for radiosurgery. The capacity for stereotactic radiosurgery equipment is approximately 350 patients per year at an average of three (3) treatments per patient and weight of 3.00 or 3,150 ESTVs per year[3]. By comparison, traditional radiation therapy protocols provide thirty (30) or more treatments per patient at approximately fifteen (15) minutes per treatment.

Additionally, the current SMFP linear accelerator need methodology generates need on a service area-wide basis rather than a facility-specific basis. Therefore, a facility that is highly utilized and at or near capacity, yet is part of a service area with other less-utilized facilities, operates at a significant disadvantage. Because the need methodology does not account for individual facility utilization levels, the well-utilized facility is thwarted from obtaining new equipment to meet established trends in patient demand.

The current linear accelerator need methodology also requires a Service Area to meet two (2) of three (3) criteria in order to generate a need. In addition to the utilization standard, one of the criterion states that a Service Area should have a

[3] Sg2 phone conversation and Proposed 2008 State Medical Facilities Plan Table 9F.

population greater than 120,000 per linear accelerator in order to generate need. With a total 2007 population of 547,202 in Service Area 12 and seven (7) existing linear accelerators, population per linear accelerator is 78,172. With projected annual population growth of 1.1% for the Service Area, this criterion will not be met until 2049, well beyond the point at which utilization exceeds capacity. Another criterion can be met when 45% or more of patients come from outside the service area. As an urban area without an academic medical center, it is unlikely that Service Area 12, in particular Moses Cone Health System will trigger this criterion. Therefore, even when utilization of existing linear accelerators reaches capacity, it is unlikely that Service Area 12 will meet either of the other two (2) criterion. It is important to note that MCHS was at 105.0% of capacity for FY 2006 and has been over 96.0% of capacity for the last five (5) years. Therefore, Service Area 12 will need its existing linear accelerators to meet demand for traditional radiation therapy, leaving no excess capacity available to meet demand for SRS.

SRS volume forecasts indicate a sufficient number of patients to justify the use of this equipment to serve the Area 12 resident population. MCHS employed a model developed by Accelitech, a company specializing in business planning and feasibility studies, to project potential SRS patient volume. Using cancer incidence rates, the assumption that 60% of all cancer patients will receive some form of radiation therapy, and the percentage of patients receiving treatment with other forms of radiation, including SRS, MCHS projects that the total number of patients in Area 12 who would be clinically appropriate to receive SRS treatments is 656 in 2007 and 695 in 2012, five years later. Table 2 provides potential SRS volumes for Area 12.

Table 2

Estimated and Projected Area 12 SRS Patients

	2007	2012	# Change	% Change
Estimated Total Potential Patient Volume	656	695	39	5.95%

Source: Accelitech Model
Moses Cone Health System

As previously stated, the capacity of SRS equipment is approximately 350 patients, or approximately half of the projected demand for SRS patient volume in Service Area 12. This capacity estimate is based on a model developed by Sg2 which employs the following assumptions: average treatment time of 140 minutes, three fractions of treatment per patient, operating 270 days per year, and10 hours per day. MCHS anticipates serving a significant portion of the projected Area 12 demand should it receive CON approval for an SRS capable linear accelerator, while a portion of the patients who live in the service area will receive treatment at other facilities that offer SRS technology. Of particular note, this projected Service Area 12 demand for SRS services matched with the capacity of SRS equipment underscores the vital need for SRS technology in this service area.

A service area population of 500,000 or more supports the need for SRS equipment that has a capacity of 350 patients annually. Table 3 presents a potential SRS patient volume scenario demonstrating that 295 patients in 2007 and 313 patients in 2012 could receive treatment at a CON approved MCHS facility. The projected 2012 patient volume is approximately 90% of capacity, thereby allowing for anticipated growth in the number of patients receiving treatment at such an SRS program.

Table 3

Service Area 12 SRS Patient Volume Scenario – 2007 and 2012

	2007	2012
Service Area 12 Population	547,202[1]	576,892[4]
Estimated SRS Patient Volumes	656[2]	695[2]
MCHS Market Share	45%[3]	45%[3]
MCHS SRS Patient Volumes	295	313
MCHS SRS Capacity Utilization[5]	84.3%	89.4%

[1] Proposed 2008 State Medical Facilities Plan, Page 113.
[2] See Table 2.
[3] Market share estimated based on current MCHS Medical Oncology market share percent.
[4] North Carolina Data Center.
[5] Based on annual capacity of 350 patients.

Source: As noted above.
Moses Cone Health System.

Alternatives Considered

Moses Cone Health System considered a number of alternatives to submitting this petition to adjust the need determination in the 2008 SMFP including maintaining the status quo, replacing an existing MCHS linear accelerator, and developing a relationship with another area radiation oncology provider. None of these options was deemed superior to submitting a petition for an adjusted need determination and, therefore, all were rejected.

Maintain the Status Quo

One alternative considered was to maintain the status quo and not pursue the acquisition of stereotactic radiosurgery (SRS) technology. This option would have the obvious advantage of eliminating the necessary capital cost. However,

this option would not allow patients in Service Area 12 to benefit from convenient access to SRS technology. Currently the closest provider of SRS treatment is located at NC Baptist Hospital in Winston-Salem, NC, which is approximately twenty-eight (28) miles from Greensboro, forty-three (43) miles from Reidsville, and almost fifty (50) miles from Eden, three of the major cities in Area 12. This distance may impede SRS referrals for many Area 12 residents. Exhibit III demonstrates excessive travel times and distances from established and CON pending SRS facilities. In addition, since SRS patients often have to return several times for treatment, a shorter travel distance will be more convenient for patients and their families.

The technology requested in this petition represents state-of-the-art technology. It can be used to treat intra and extracranial tumors, thus serving a large and expanding pool of potential patients. Moreover, SRS technology provides improved accuracy in targeting the tumor which greatly reduces damage to the surrounding, healthy tissue.

Replace an Existing MCHS Linear Accelerator

Replacement of an existing MCHS linear accelerator with SRS technology was also considered. Due to the high utilization levels of MCHS's four (4) existing linear accelerators, replacing an existing linear accelerator with SRS technology would significantly reduce capacity for serving radiation oncology patients. Table 4 lists the utilization of MCHS's existing linear accelerators.

Table 4

Moses Cone Health System Linear Accelerator Volumes FY 2002 – 2006

						Change FY 02-06	
	FY 2002	**FY 2003**	**FY 2004**	**FY 2005**	**FY 2006**	**#**	**%**
ESTVs	26,883	28,947	26,097	26,824	28,362	1,480	5.5%
# of Linear Accelerators	4	4	4	4	4	0	0.0%
ESTVs/Linear Accelerator	6,721	7,237	6,524	6,706	7,091	370	5.5%
% Utilization [1]	99.6%	107.2%	96.7%	99.3%	105.0%	5.5%	5.5%

Note: ESTV = Equivalent Single Treatment Visit

[1] Based on the annual capacity of 6,750 ESTV procedures, as set in the State Medical Facilities Plan.

Source: Annual Hospital License Renewal Applications

MCHS has been above 96% capacity since FY 2002 and for FY 2006 was operating at 105% of capacity.

As previously described, SRS patients are best served through equipment dedicated to providing SRS services. MCHS's historically high utilization of its existing linear accelerator capacity simply does not permit the replacement of one of these machines with a SRS capable linear accelerator. Under this scenario, both radiation oncology and SRS patients would suffer from unacceptable wait times for treatment.

Develop a Relationship with Another Area Radiation Oncology Provider

Moses Cone Health System also considered developing a relationship with another area radiation oncology provider. Table 5 lists close hospitals that provide radiation oncology services, the number of unduplicated patients treated, and the number of ESTV procedures performed in FY 2006.

Table 5

Selected North Carolina Hospitals Providing Radiation Oncology Services

	FY 2006	
Radiation Oncology Provider	**Number of Unduplicated Patients**	**Number of ESTV Procedures**
Moses Cone Health System	1,080	28,362
High Point Regional Health System	389 [1]	9,623[1]
Morehead Memorial Hospital	217	5,972
Alamance Regional Medical Center	305	7,991

[1] From 2006 Hospital License Renewal Application, p. 14 and 15 due to an apparent inconsistency in the 2007 Application as compared to other years, for the number of unduplicated patients.

Source: 2007 Hospital License Renewal Applications, p. 14 and 15.

Currently within Area 12, there are two other radiation oncology providers, High Point Regional Health System and Morehead Memorial Hospital. Neither of these programs have the scope and comprehensiveness of services necessary to develop a SRS program. Alamance Regional Medical Center, while outside Service Area 12 but located close to Moses Cone Health System, also lacks the capacity to serve additional SRS patients. The aforementioned hospitals are small to medium sized community hospitals and do not have the size, technological infrastructure, and breadth of physician specialties on staff to be a viable partner with MCHS to develop a SRS program. Supporting this conclusion, please see Exhibit IV for letters from High Point Regional Health System and Morehead Memorial Hospital supporting this petition.

The closest SRS provider to Area 12 is NC Baptist Hospital, located in Winston-Salem. UNC Hospital, the next closest facility that provides SRS treatments is fifty-six (56) miles from Greensboro, a distance which would cause referral and travel difficulties for patients in need of treatment.

After thoroughly examining these three alternatives, MCHS decided that submitting this petition was the best option to provide Area 12 residents with state-of-the-art technology within close proximity to their homes and without

reducing capacity for patients in need of highly utilized, traditional radiation treatments.

No Unnecessary Duplication of Health Care Resources

The addition of a need determination for a linear accelerator with SRS capability will not result in unnecessary duplication of health care resources for the following reasons:

1. Linear Accelerator Service Area 12 currently contains no SRS capable equipment. MCHS and its physicians are uniquely qualified to offer this service by expanding its well-established, well-utilized radiation oncology program.
2. MCHS's existing linear accelerators are operating above 100% capacity (6,750 ESTVs/linear accelerator) as noted in Table 4.
3. Patient volumes for SRS, both intra and extracranial, will grow substantially over the coming years due to the clinical applications of the technology and the expected growth in incidence of cancers that may benefit from treatment using SRS.
4. The current linear accelerator need methodology is service area based. Hence, it penalizes those providers who operate at high utilization while other service area providers do not. This situation limits a well-utilized program from upgrading existing equipment without incurring negative consequences for existing patients and clinical needs.

Adjusted Need Determination Request

Moses Cone Health System respectfully requests that the 2008 State Medical Facilities Plan include an adjusted need determination for a linear accelerator providing stereotactic radiosurgery capabilities in Service Area 12 based on the following criteria:

1. The Service Area 12 2007 resident population exceeds 500,000, a size sufficient to support a stereotactic radiosurgery program.

2. As documented in the Proposed 2008 State Medical Facilities Plan, Moses Cone Health System provided linear accelerator services above the performance threshold of 6,750 ESTVs per linear accelerator for FY 2006.
3. No stereotactic radiosurgery providers exist in Service Area 12. Moreover, the potential for establishing the need for a linear accelerator with SRS capability, absent an adjusted need determination, will not occur for many years to come.

EXHIBIT I

MOSES CONE [illegible]

Regional Cancer Center

501 North Elam Avenue
Greensboro NC 27403-1199

Writer's Direct Number

August 3, 2007

Ms. Elizabeth Brown, Chief
Medical Facilities Planning Section
The Division of Health Service Regulation
North Carolina Department of Health and Human Services
2714 Mail Service Center
Raleigh, North Carolina 27699-2714

Dear Ms. Brown:

I am pleased to support the petition for an adjusted need determination submitted by Moses Cone Health System (MCHS) requesting the addition of a linear accelerator with stereotactic radiosurgery (SRS) capabilities in service area 12 (Guilford and Rockingham Counties) to the 2008 State Medical Facilities Plan. As a practicing physician, I have first hand knowledge of how SRS could benefit my patients, and I firmly believe a variety of reasons justify the approval of Moses Cone's petition for Service Area 12.

Service area 12 has a large population and one linear accelerator provider, MCHS, which is operating above capacity. If MCHS were to replace an existing linear accelerator with SRS equipment, it would significantly reduce capacity, as throughput on SRS machines is much lower than on traditional linear accelerators. This would cause a significant barrier to access for patients in need of traditional radiation treatments as well as SRS, a new, cutting-edge technology. Therefore, we believe adding need for a linear accelerator with SRS technology is the only way to ensure high quality, accessible care to the residents of service area 12.

SRS is one of the fastest-growing areas of oncologic radiation therapy. As Radiation Oncologists, we are acutely aware of the increasing utilization of SRS therapies in treating a growing number of cancers. SRS provided via a linear accelerator now enables the delivery of high doses of radiation to intracranial tumors without a metal head frame and to extracranial tumors such as the spine, lung, prostate, liver, and pancreas, while maintaining and even improving submillimeter accuracy to target the tumor or lesion. Intercranial utilization of SRS is projected to increase based on several factors: the technology can be used for patients with multiple or recurrent brain lesions once thought to be untreatable; clinical efficacy will continue to improve for non-cancer indications, such as functional disorders and acoustic neuromas; treatment of brain metastases will increase due to improved survival rates for other primary cancers; and the increasing public awareness and interest in receiving state-of-the-art care.

We appreciate the opportunity to offer our support for this important petition, and we look forward to the Medical Facilities Planning Section's approval of the adjusted need determination for the addition of need for a linear accelerator with SRS capabilities in service area 12.

Sincerely,

Robert Murray, M.D.

MOSES CONE

Regional Cancer Center

501 North Elam Avenue
Greensboro NC 27403-1082

Writer's Direct Number

August 3, 2007

Ms. Elizabeth Brown, Chief
Medical Facilities Planning Section
The Division of Health Service Regulation
North Carolina Department of Health and Human Services
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We appreciate the opportunity to offer our support for this important petition, and we look forward to the Medical Facilities Planning Section's approval of the adjusted need determination for the addition of need for a linear accelerator with SRS capabilities in service area 12.

Sincerely,

James Kinard, M.D.

MOSES CONE

Regional Cancer Center

501 North Elam Avenue
Greensboro NC 27403-1199

Writer's Direct Number

August 3, 2007

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Medical Facilities Planning Section
The Division of Health Service Regulation
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As Oncologists, we are acutely aware of the increasing utilization of SRS therapies in treating a growing number of cancers. We currently refer patients each year to SRS providers outside of area 12. We are acutely aware of the hardship this causes our patients who must make multiple trips to receive treatment.

We appreciate the opportunity to offer our support for this important petition, and we look forward to the Medical Facilities Planning Section's approval of the adjusted need determination for the addition of need for a linear accelerator with SRS capabilities in service area 12.

Sincerely,

John Feldmann, M.D.

MOSES CONE

Regional Cancer Center

501 North Elam Avenue
Greensboro NC 27403-1199

Writer's Direct Number

August 3, 2007

Ms. Elizabeth Brown, Chief
Medical Facilities Planning Section
The Division of Health Service Regulation
North Carolina Department of Health and Human Services
2714 Mail Service Center
Raleigh, North Carolina 27699-2714

Dear Ms. Brown:

I am pleased to support the petition for an adjusted need determination submitted by Moses Cone Health System (MCHS) requesting the addition of a linear accelerator with stereotactic radiosurgery (SRS) capabilities in service area 12 (Guilford and Rockingham Counties) to the 2008 State Medical Facilities Plan. As a practicing physician, I have first hand knowledge of how SRS could benefit my patients, and I firmly believe a variety of reasons justify the approval of Moses Cone's petition for Service Area 12.

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Sincerely,

Peter Rubin, M.D.

MOSES CONE

Regional Cancer Center

501 North Elam Avenue
Greensboro, NC 27403-1199

Writer's Direct Number

August 3, 2007

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Medical Facilities Planning Section
The Division of Health Service Regulation
North Carolina Department of Health and Human Services
2714 Mail Service Center
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Sincerely,

G. Bradley Sherrill, M.D.

Guilford Neurosurgical Associates, P.A.
1313 Carolina Street, Suite 300
Greensboro, NC 27401
Telephone (336) 272-4578
Fax (336) 272-5931

Ernesto M. Botero, M.D., F.A.C.S.*
Robert W. Nudelman, M.D., F.A.C.S.*
Henry J. Elsner, M.D., F.A.C.S.*
Mark W. Roy, M.D., Ph.D.*
Jeffrey D. Jenkins, M.D., F.A.C.S.*
Kyle L. Cabbell, M.D.*
Joseph D. Stern, M.D., F.A.C.S.*
James R. Hirsch, M.D.*

*Diplomates of the American Board of Neurological Surgery

August 3, 2007

Ms. Elizabeth Brown, Chief
Medical Facilities Planning Section
The Division of Health Service Regulation
North Carolina Department of Health and Human Services
2714 Mail Service Center
Raleigh, North Carolina 27699-2714

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We appreciate the opportunity to offer our support for this important petition, and we look forward to the Medical Facilities Planning Section's approval of the adjusted need determination for the addition of need for a linear accelerator with SRS capabilities in service area 12.

Sincerely,

Henry Elsner, MD

Robert Nudelman, MD

Mark Roy, MD

Jeffrey Jenkins, MD

Kyle Cabbell, MD

James Hirsch, MD

August 2, 2007

Ms. Elizabeth Brown, Chief
Medical Facilities Planning Section
The Division of Health Service Regulation
North Carolina Department of Health and Human Services
2714 Mail Service Center
Raleigh, North Carolina 27699-2714

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cancers; and the increasing public awareness and interest in receiving state-of-the-art care.

We appreciate the opportunity to offer our support for this important petition, and we look forward to the Medical Facilities Planning Section's approval of the adjusted need determination for the addition of need for a linear accelerator with SRS capabilities in service area 12.

Sincerely,

Randy O. Kritzer, M. D.
Neurosurgeon
Carolina Neurosurgery, P.A.
301 E. Wendover Ave, Suite 211
Greensboro, NC 27401

August 2, 2007

Ms. Elizabeth Brown, Chief
Medical Facilities Planning Section
The Division of Health Service Regulation
North Carolina Department of Health and Human Services
2714 Mail Service Center
Raleigh, North Carolina 27699-2714

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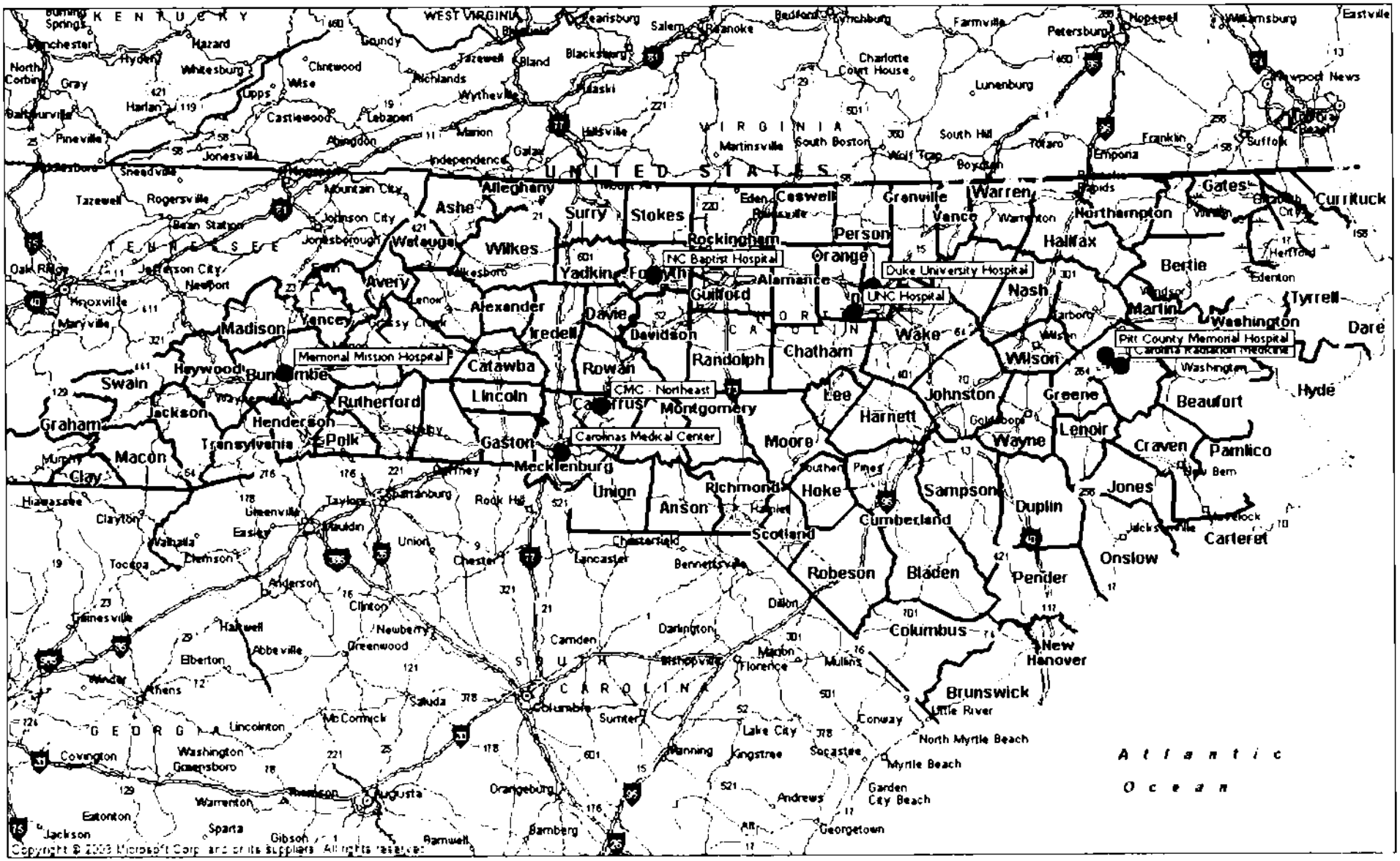
We appreciate the opportunity to offer our support for this important petition, and we look forward to the Medical Facilities Planning Section's approval of the adjusted need determination for the addition of need for a linear accelerator with SRS capabilities in service area 12.

Sincerely,

David Jones, M. D.
Neurosurgeon
Carolina Neurosurgery, P.A.
301 E. Wendover Ave, Suite 211
Greensboro, NC 27401

EXHIBIT II

Exhibit II
Existing SRS Locations in North Carolina



Linear Accelerator Service Area 12

EXHIBIT III

Exhibit III
Distance and Travel Times to Existing SRS Facilities

	Area 12 Major Cities			
	Greensboro (Guilford Co.)	**High Point (Guilford Co.)**	**Reidsville (Rockingham Co.)**	**Eden (Rockingham Co.)**
Carolinas Med Center, Charlotte	94.5 miles 1 hour, 41 minutes	84.2 miles 1 hour, 27 minutes	118.5 miles 2 hours, 6 minutes	131.0 miles 2 hours, 24 minutes
CMC - Northeast, Concord	69.7 miles 1 hour, 15 minutes	59.3 miles 1 hour	93.6 miles 1 hour, 40 minutes	106.1 miles 1 hour, 58 minutes
Carolina Radiation Medicine, Greenville	162.3 miles 2 hours, 53 minutes	176.2 miles 3 hours, 3 minutes	182.6 miles 3 hours, 15 minutes	202.2 miles 3 hours, 48 minutes
Duke University Hospital, Durham	52.1 miles 58 minutes	65.9 miles 1 hour, 9 minutes	64.8 miles 1 hour, 19 minutes	77.3 miles 1 hour, 38 minutes
Memorial Mission Hospital, Asheville	169.8 miles 2 hours, 47 minutes	161.4 miles 2 hours, 39 minutes	194.3 miles 3 hours, 16 minutes	192.1 miles 3 hours, 27 minutes
NC Baptist Hospital, Winston-Salem	27.9 miles 35 minutes	22.0 miles 29 minutes	43.3 miles 55 minutes	47.9 miles 1 hour, 11 minutes
Pitt County/Brody School, Greenville	161.0 miles 2 hours, 51 minutes	174.8 miles 3 hours, 2 minutes	181.2 miles 3 hours, 13 minutes	200.9 miles 3 hours, 46 minutes
UNC Chapel Hill, Chapel Hill	56.0 miles 1 hour, 3 minutes	69.9 miles 1 hour, 14 minutes	68.8 miles 1 hour, 24 minutes	81.2 miles 1 hour, 42 minutes

Source: Microsoft MapPoint 2004

EXHIBIT IV

High Point Regional Health System

Jeffrey S. Miller
President

August 2, 2007

Ms. Elizabeth Brown, Chief
Medical Facilities Planning Section
The Division of Health Service Regulation
North Carolina Department of Health and Human Services
2714 Mail Service Center
Raleigh, NC 27699-2714

Dear Ms. Brown:

I understand that Moses Cone Health System is submitting a petition requesting an adjusted need determination for the 2008 State Medical Facilities Plan to add a linear accelerator with stereotactic radiosurgery capabilities to Service Area 12.
High Point Regional Health System is one of the three established providers of radiation oncology services in Linear Accelerator Service Area 12. I believe the residents of Guilford and Rockingham counties could greatly benefit by gaining greater access to stereotactic radiosurgery services. Moreover, it appears that petitioning for an adjusted need determination is the most effective approach for establishing the need for this valuable technology. I urge the State Health Coordinating Council to approve the petition submitted by Moses Cone Health System.

Sincerely,

Jeffrey S. Miller
President

601 N. Elm Street • P.O. Box HP-5
High Point, North Carolina 27261
Telephone (336) 878-6960
Fax (336) 878-6158

MOREHEAD
MEMORIAL·HOSPITAL

August 3, 2007

Ms. Elizabeth Brown, Chief
Medical Facilities Planning Section
The Division of Health Service Regulation
North Carolina Department of Health and Human Services
2714 Mail Service Center
Raleigh, North Carolina 27699-2714

Dear Ms. Brown,

I understand that Moses Cone Health System is submitting a petition requesting an adjusted need determination for the 2008 State Medical Facilities Plan to add a linear accelerator with stereotatic radiosurgery capabilities to Service Area 12. Morehead Memorial Hospital is one of the three established providers of radiation oncology services in Linear Accelerator Service Area 12. This new linear accelerator will not take volume from any of the existing facilities as it will be a dedicated unit only used for stereotatic radiosurgery, a service currently not available in Service Area 12. I believe the residents of Guilford and Rockingham counties could greatly benefit by gaining greater access to stereotatic radiosurgery services. Moreover, it appears that petitioning for an adjusted need determination is the most effective approach for establishing the need for this valuable technology. I urge the State Health Coordinating Council to approve the petition submitted by Moses Cone Health System.

Sincerely,

Robert A. Enders, Jr.
President

117 East Kings Highway
Eden, North Carolina 27288-5201
TEL 336.623.9711
www.morehead.org

Radiation Oncology Services -

Top of Document

Technology and Equipment Committee Meeting

August 29, 2007

Radiation Oncology Services - Linear Accelerators

Comments Related To

Linac Petition-1: Moses Cone Health System

Comment -1 Jim Whiting
Comment -2 Dr. Henry A. Pool

Greensboro PH
7-20-07
LinAC
Tom

Proposed 2008 State Medical Facilities Plan

Public Hearing

July 20, 2007

Moses Cone Health System

Remarks Made Supporting an Adjusted

Need Determination for a Linear Accelerator

with Stereotactic Radiosurgery Capability

in Service Area 12

Good Afternoon. My name is Jim Whiting, and I am the Vice President for Moses Cone Health System's Regional Cancer Center. My remarks today address the need to provide immediate access to Stereotactic Radiosurgery (SRS) technology for the residents of linear accelerator Service Area 12 comprising Guilford and Rockingham counties. Serving this unmet need is essential to insuring a full array of state-of-the-art therapy services to this region's population, which currently totals over 541,000 residents. However, existing State Medical Facilities Plan need methodologies effectively block the addition of SRS technology in our area. As a result, Moses Cone Health System intends to submit a petition for an adjusted need determination for the addition of a linear accelerator with SRS capabilities.

Our petition will be based on the following major points:

1. Stereotactic radiosurgery is both a proven and expanding modality for the treatment of both intra and extra cranial tumors.

2. Physicians directly involved with the care of patients who could benefit most from SRS, most notably neurosurgeons, thoracic surgeons and radiation oncologists on staff at Moses Cone Health System, strongly support the addition of this technology.

3. Current geographic access to SRS services for Area 12 residents is limited.

- No SRS providers exist in Guilford or Rockingham counties.

- While other service areas provide SRS, travel to these programs imposes a burden on Area 12 patients and families.

4. The Service Area 12 resident population is of a sufficient size, greater than 500,000, to warrant the development of a SRS program.

5. The current SMFP need methodology for linear accelerators is area and not provider specific. As a result, lower utilized facilities in a given service area can prevent the determination of an identified need despite one or more providers operating at or above capacity.

   This situation is currently found in Area 12, where MCHS operates at over 100% capacity on its four (4) linear accelerators, while Morehead Memorial Hospital and High Point Regional Health System operate at 79.9% and 69.2%, respectively.

6. MCHS has considered a number of alternatives to requesting an adjusted need determination:

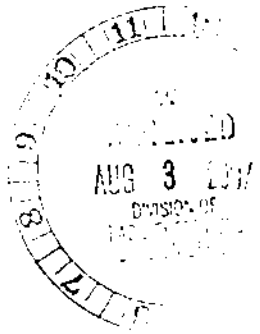
   - The status quo fails to meet the unmet need for SRS services.

   - Replacing an existing linear accelerator at MCHS with a stereotactic radiosurgery machine significantly reduces MCHS radiation oncology capacity. SRS patients require longer treatment times; a machine dedicated to SRS will best meet the clinical needs of these patients.

7. No unnecessary duplication of services will result from the approval of this adjusted need determination. Indeed, our petition is based on the current lack of SRS capabilities in Area 12.

Our petition will expand on each of these major points. I am hopeful that the Medical Facilities Planning Section staff and the State Health Coordinating Council will look favorably at our request.

Thank you.



August 3, 2007

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The Division of Health Service Regulation
North Carolina Department of Health and Human Services
2714 Mail Service Center
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We appreciate the opportunity to offer our support for this important petition, and we look forward to the Medical Facilities Planning Section's approval of the adjusted need determination for the addition of need for a linear accelerator with SRS capabilities in service area 12.

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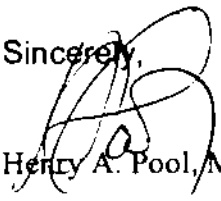


Henry A. Pool, M.D.

Top of Document

Technology and Equipment Committee Meeting

August 29, 2007

Radiation Oncology Services - Linear Accelerators

Material Related To

Linac Petition-2: Cape Fear Valley Health System

PETITION FOR A SPECIAL NEED DETERMINATION FOR A CYBERKNIFE STEREOTACTIC RADIOSURGERY SYSTEM IN THE PROPOSED 2008 STATE MEDICAL FACILITIES PLAN FOR LINEAR ACCELERATOR AREA 18

PETITIONER

Lynda B. Clark, Vice President for Professional Services
Cape Fear Valley Health System
1638 Owen Drive
Fayetteville North Carolina 28302-2000
910/609-6549

STATEMENT OF THE REQUESTED ADJUSTMENT

Cape Fear Valley Health System ("Cape Fear Valley") submits this petition for an adjustment in the Proposed 2008 State Medical Facilities Plan ("SMFP") to recognize a special need determination for a CyberKnife Stereotactic Radiosurgery System in linear accelerator area 18 ("Area 18")[1].

We concur with the preliminary determination from the Technology and Equipment Committee noted on May 24, 2007 that based on the SMFP need determination methodology there is no need for an additional linear accelerator in the state. We also agree with the Technology Committee that no additional GammaKnife is needed in the state.

Based on information provided on the following pages, Cape Fear Valley respectfully requests that consideration be given to a special need determination in Area 18 for the development of a CyberKnife Stereotactic Radiosurgery System based on the unique needs of the area.

REASONS FOR THE PROPOSED ADJUSTMENT

History of Stereotactic Radiosurgery

Stereotactic Radiosurgery (SRS) is a highly precise form of radiation therapy delivered in a single high-dose session with effects so dramatic it is considered surgical in nature. Stereotactic Radiotherapy (SRT) is similar in effect but fractionated, meaning 2-5 treatments instead of just one treatment. SRS and SRT have been used historically to treat certain types of malignant and non-malignant brain tumors, brain malformations, inoperable brain tumors, as well as recurrent brain tumors. Until recently, almost all SRS and SRT was limited to intracranial (brain and upper spine) lesions using head frames bolted to a patient's skull as well as the treatment table to immobilize the patient for treatment. SRS and SRT

[1] Area 18 in the SMFP includes Cumberland, Bladen, Robeson and Sampson counties.

treatments for intracranial lesions have traditionally been performed using linear accelerators modified to deliver these precise treatments, proton therapy units found only in a few locations in the world, and Cobalt-60 dedicated units known as a GammaKnife.[2]

Stereotactic Radiosurgery (SRS) has been around for many years, though mainly in university settings. SRS/SRT programs have historically been provided by academic medical centers due to the enormous financial and physical resources required for the lengthy procedures and research. At the opposite end of the linear accelerator spectrum, community hospital settings have neither the financial nor physical resource backing for research, especially the excess capacity needed on their linear accelerators to perform SRS/SRT. Thus, SRS/SRT programs have mainly been limited to the university setting. As an example, typical SRS patient treatments take multiple hours to perform: first, attaching the headframe to the skull or preparing immobilization devices; second, imaging the treatment area; third, performing the computerized treatment plan; and finally, treating the patient. All of these processes take place with the patient lying on an uncomfortable treatment table and over multiple hours. Staff must be present throughout most of the procedures including radiation oncologists, physicists, dosimetrists, nurses, radiation therapists, and other support staff. During this long process, the linear accelerator cannot be used for external beam radiation therapy ("EBRT") treatments, tying up valuable resources for an extended period of time.

In the early 2000's, a revolutionary SRS/SRT unit was developed called CyberKnife and with it SRS/SRT services began expanding beyond the academic medical center setting. CyberKnife contains a small linear accelerator mounted on a robotic arm that delivers high doses of radiation anywhere in the body without invasive headframes bolted to skulls or other invasive immobilization. This astounding technology accomplishes this mission that no other SRS/SRT product has done (intra and extracranial treatments with little or no immobilization) by visually tracking the tumor during treatment and moving with the tumor for the entirety of the treatment. CyberKnife is an SRS/SRT dedicated unit used solely to treat intracranial and extracranial lesions anywhere in the body, and like the GammaKnife, is not capable of performing typical EBRT, the most common procedures performed with linear accelerators. CyberKnife represents a phenomenal breakthrough for SRS and SRT, for which there is no comparison.

In contrast to traditional SRS/SRT technology, CyberKnife requires no invasive immobilization procedures to be performed, imaging and treatment planning are done on the virtual patient prior to the day of treatment and patient treatments generally take only 30-90 minutes depending on the tumor volume treated and the tumor location. Because of this, CyberKnife procedures in established centers range from 4-7 patient treatments a day. Intracranial tumors are typically treated and completed in just one treatment with CyberKnife. Extracranial tumors

[2] Currently, Wake Forest University Baptist Medical Center and Pitt County Memorial Hospital operate GammaKnife equipment. The following providers have SRS/SRT modified linear accelerators: Carolinas Medical Center (1), Duke (2), Memorial Mission (1), Pitt County Memorial Hospital (2), UNC (1), Wake Forest (1), Carolina Radiation Medicine (1).

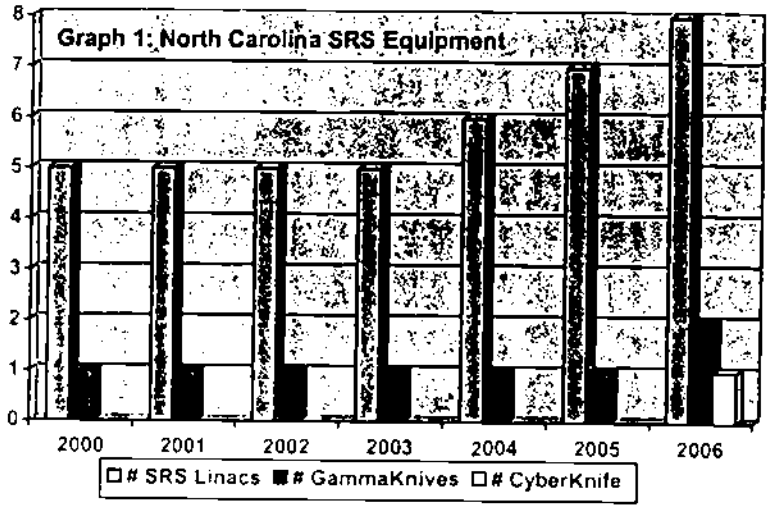
generally range from 3-5 treatments with CyberKnife to complete their treatment course. The resource allocation for CyberKnife still requires the same staff members to participate in the SRS/SRT process; however, less time commitment per patient and greater flexibility with planning yields, greater efficiency and the ability to treat more patients daily as compared to traditional linac-based SRS/SRT.

CyberKnife can easily treat 350 new SRS/SRT patients annually, as evidenced by successful programs throughout the United States, many of which are in community hospital settings and installing second CyberKnife units. The compelling and undisputable evidence nationwide shows that traditional linac-based SRS/SRT programs simply are not widely adopted nor widely used due to the multitude of inefficiencies noted earlier, even on dedicated SRS/SRT units. Clearly, CyberKnife affords the greatest SRS/SRT utilization and efficiency in the market today. Even more compelling than the efficiencies gained is that CyberKnife is designed for a different population of patients than those receiving traditional EBRT, a population largely receiving less optimal treatment or no treatment at all.

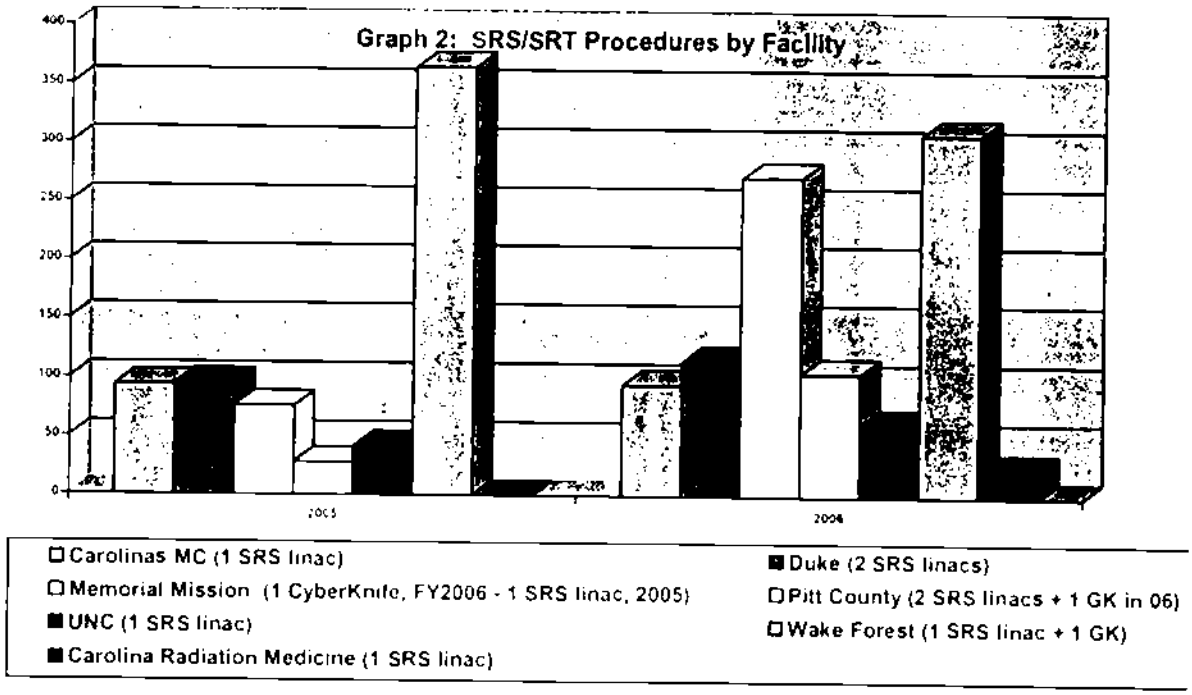
Currently CyberKnife services are provided at Memorial Mission Hospitals (Asheville) and Northeast Medical Center (Concord). UNC Hospitals (Chapel Hill) has been approved for the service and East Carolina University (Greenville) has applied for approval.

Recent NC Experience with Stereotactic Radiosurgery

According to the 2007 SMFP, there were eight operational SRS/SRT units in 2005 that performed a total of 700 SRS/SRT procedures on seven linac-based SRS units and one GammaKnife unit. According to the draft 2008 SMFP, there were 982 SRS/SRT procedures performed on eleven operational SRS/SRT units in 2006, including eight linac-based units, one CyberKnife, and two GammaKnife units. Graph 1 below distinguishes the number and type of SRS/SRT equipment installed and functional in North Carolina from 2000-2006.



The chart below shows the number of SRS/SRT procedures at each of the facilities operating SRS/SRT equipment. The clear leaders in SRS/SRT treatments performed in North Carolina are Wake Forest using GammaKnife for the majority of their SRS/SRT procedures and Memorial Mission using CyberKnife for 100 percent of their SRS/SRT. None of the linac-based providers performed substantial SRS/SRT procedures compared to the dedicated SRS/SRT GammaKnife and CyberKnife units.



The graph and table below show the growth in SRS/SRT over the past seven years and the low number of procedures performed on Linac SRS units as compared to dedicated SRS/SRT units (GammaKnife and CyberKnife). In one year a single CyberKnife unit performed almost as many SRS/SRT procedures as eight Linac SRS units.

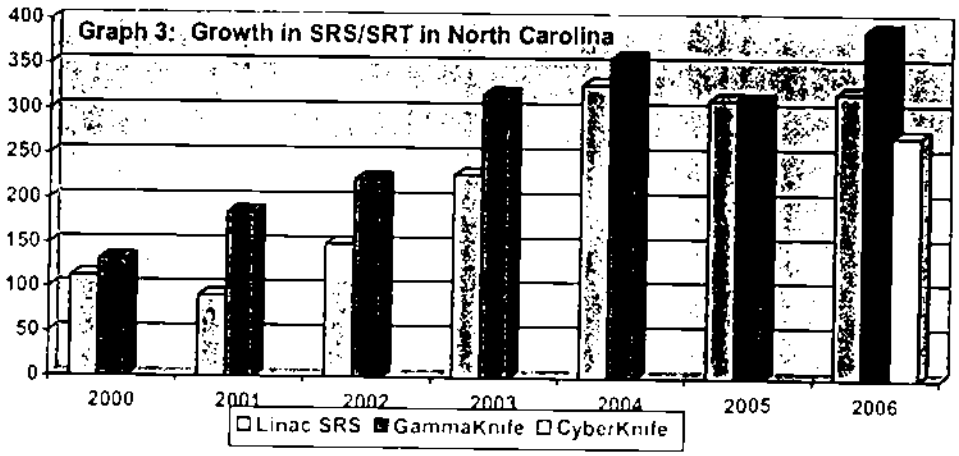


Table 1 – SRS Utilization by Type SRS Equipment

Data Year	SRS In-Use Linacs	Linac SRS Proc	Avg SRS Per Linac	Cyber #	Cyber SRS Proc	Avg SRS Per Cyber	Gamma #	SRS Gamma Proc	Avg SRS Per Gamma	State Linac Volumes
2000	5	113	23				1	132	132	512,578
2001	5	91	18				1	185	185	558,311
2002	5	150	30				1	223	223	553,506
2003	5	228	46				1	318	318	556,321
2004	6	329	55				1	358	358	556,224
2005	7	388	55				1	312	312	577,262
2006	8	320	40	1	272	272	2	390	195	573,184
Seven Years Cumulative		1,619			272			1,918		3,887,386

For the reporting year 2007, three CyberKnife units will be operational in North Carolina with projected volumes greater than 500 procedures, exceeding volumes performed on either GammaKnife or Linac SRS units in 2006. CyberKnife is expected to experience such growth because it is the only system uniquely able to combine continuous image guidance, automatic correction with computer controlled robotics, minimal (if any) immobilization requirements, and ability to deliver ablative radiosurgery with sub-millimeter accuracy anywhere in the body with minimal to no side effects.

The only site in North Carolina to date with CyberKnife experience is Memorial Mission, which experienced no reduction in EBRT volumes when a CyberKnife was added, as shown in Table 2 below.

Table 2 – Equivalent Simple Treatment Visits ("ESTVs") 2007 and Proposed 2008 SMFP

Memorial Mission ESTVs	FY2005	FY2006	Increase in FY2006
Excluding CyberKnife ESTVs	19,569	19,949	380
Including CyberKnife ESTVs	19,569	20,766	1,197

Linear Accelerator Need Determination in Area 18

Currently, 112 linear accelerators are in operation or are planned for development in North Carolina. Five linear accelerators operate in Area 18, three at Cape Fear Valley Medical Center (Cape Fear Valley's main campus in Fayetteville), one at Health Pavilion North (Cape Fear Valley's north Cumberland County outpatient facility) and one at Southeastern Regional Medical Center in Lumberton, North Carolina. The need methodology in the SMFP requires meeting two of three of the following criteria before a need is established:

1) Population per accelerator is 120,000 or more;
2) More than 45% of the patients served by the Area's linear accelerators are residents from outside the Area;

3) Equivalent Simple Treatment Visits ("ESTVs") divided by 6.750 (linear accelerator capacity as defined by the SMFP) less the number of existing accelerators in the Area is greater than or equal to .25.

Area 18 meets Criteria 3 and actually shows a +.50 need determination in the proposed 2008 SMFP, but does not meet Criteria 1 or 2 (Area 18 population per accelerator = 107,401; 12% of patients reside outside Area 18). Therefore, no need is established in Area 18 for an additional linear accelerator.[3] Also, the 2006 and 2007 SMFP determined no need for an additional linear accelerator in Area 18.

In November 2006, Cape Fear Valley submitted an application for the acquisition of CyberKnife equipment to provide SRS/SRT services. The application was denied by the CON Section based on its interpretation that a CyberKnife is subject to the regular need methodology. It should be noted that GammaKnife equipment, which is used only for SRS intracranial treatments, is not subject to this linear accelerator need methodology. Likewise, CyberKnife can only be used for SRS/SRT intracranial and extracranial treatments and cannot perform EBRT treatments. As described more fully below, there is a critical need for SRS/SRT services in Southeastern North Carolina where currently no providers offer this service. Given the need for the service and the clinical expertise, resources and capabilities present at Cape Fear Valley to support the service, a special need should be determined for a dedicated SRS/SRT program in Area 18.

Special Needs of Area 18

A number of North Carolina communities will gain access to CyberKnife technology by replacing existing linear accelerators. UNC Hospitals is replacing an existing low-utilization linear accelerator with a CyberKnife unit and East Carolina University proposes to do the same. Under these circumstances, need in the SMFP is not required because existing equipment is being replaced, though clearly these units are dissimilar. Such a replacement would be similar to replacing an outdated cobalt unit with a GammaKnife.

Replacing an existing linear accelerator in Area 18 is not an option available to providers because existing demand for Area 18 linear accelerators already exceeds the capacity threshold in the SMFP methodology. Of the 27 SMFP linear accelerator areas, only one other, area 17[4], exceeds the capacity threshold by more than .25 as required in the linear accelerator need methodology. As noted previously, CyberKnife is a dedicated unit that is capable of performing only SRS/SRT. SRS/SRT is a critical need in southeastern North Carolina and represents a new treatment choice for a largely new population of patients in this region. Replacing a currently fully utilized linear accelerator in order to gain a CyberKnife would limit EBRT treatment capacity and is certainly not in the best interest of the patients we serve.

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[3] The SMFP also does not establish a linear accelerator need in any other Area.

[4] Area 17 has a population of approximately 295,400 residents and includes Moore, Hoke, Lee, Montgomery, Scotland and Richmond counties

Recent experience in Area 18 indicates that as linear accelerators are added capacity is quickly absorbed. When Cape Fear's fourth linear accelerator became operational at Health Pavilion North in Fayetteville in fiscal year 2006, the unit was operating at full capacity within five months. According to the SMFP linear accelerator need determination methodology, a fully utilized linear accelerator performs 6,750 ESTVs annually. For the 2006 reporting period, Cape Fear Valley actually performed 27,631 ESTVs on 4 linear accelerators, or 6,908 ESTVs per unit, even with the fourth linear accelerator operational for only five months of the reporting year. For Area 18, 37,115 ESTVs were performed in 2006 on five accelerators or 7,423 ESTVs per unit owned by Cape Fear Valley or through contracted services with Southeastern Regional Medical Center. Growth of EBRT, the most common radiation treatments, is only expected to continue, meaning that Cape Fear Valley will likely need to add more traditional linear accelerators if there is future need determined in the SMFP.

Moreover, Area 18 has a large population of over 537,000 people, which is more than adequate to support a dedicated SRS/SRT service. No other linear accelerator service area in the State has a large enough population to support a dedicated SRS/SRT service coupled with the lack of capacity in existing linear accelerator units, precluding the ability to replace an existing EBRT linear accelerator with a CyberKnife. In the letter under Attachment 1, Dr. Hugh Bryan, Medical Director of Cape Fear Valley's Radiation Oncology department describes SRS, the need for the service in Area 18 and how SRS patients are different from other radiation therapy candidates.

Also, attached are letters from other radiation oncologists in the country addressing the differences between external beam therapy and SRS. Attachment 2 includes a letter from Dr. Mark J. Brenner, Chief of Radiation Oncology at Sinai Hospital in Baltimore. Sinai has treated over 1,000 patients with CyberKnife technology and recently started utilizing its second unit. Attachment 3 includes a letter from Dr. Clinton A. Medbery, President of Southwest Radiation Oncology in Oklahoma City, also noting that that CyberKnife SRS is not a replacement for standard linear accelerator treatments.

Projected Demand for CyberKnife in Area 18

As noted in Table 3 below, Cape Fear Valley projects that an Area 18 CyberKnife will annually serve approximately 250 patients and provide approximately 620 CyberKnife treatments by the third year of operation in addition to more than 19,000 projected EBRT linear accelerator treatments. This is a conservative estimate based on Cape Fear Valley 2006 radiation therapy patients with specific types of inoperable cancer or who have incurred maximum radiation treatments for their lesions (see Table 4 below). This extraordinary need cannot be met with traditional linear accelerator equipment, but requires stereotactic radiosurgery technology. This request for a CyberKnife stereotactic radiosurgery system in Area 18 is required to meet the critical needs of well over 500,000 residents in our four-county service area.

Table 3 -- Cape Fear Valley Projections						
Data Year	Linacs	Linac Patients	Linac Treatments (not ESTVs)	Cyber-Knives	CyberKnife Patients	CyberKnife Treatments
2006 Actual	4[1]	893	17,388			
2007 Projected	4	911	17,736			
2008 P	4	929	18,091			
2009 P	4	948	18,452	1	150	375
2010 P	4	967	18,821	1	200	500
2011 P	4	986	19,198	1	250	620

(1) Fourth Linear accelerator became operational in May 2006

Table 4 Cape Fear Valley CyberKnife Candidates In 2006			
AREA TREATED	# OF PATIENTS TREATED WITH EXTERNAL BEAM RADIATION AT CAPE FEAR VALLEY	% TREATABLE WITH CYBERKNIFE	TOTAL CYBERKNIFE CANDIDATES
Primary malignant Head and Neck tumors	48 patients	40%	19
Primary malignant Brain tumors	29 patients	30%	9
Primary lung tumors	90 patients	30%	27
Metastatic lung tumors	39 patients	25%	10
Pancreatic tumors	10 patients	75%	8
Renal tumors	5 patients	30%	2
Prostate cancer	139 patients	50%	70
Total	426 patients		178

Over 200 peer reviewed papers and book chapters have been published from 1991 through 2007 regarding CyberKnife SRS and its efficacy for the treatment areas noted above. Cape Fear Valley will provide a clinical dossier of the publications to the Planning Section upon request.

ADVERSE EFFECTS ON THE POPULATION OF THE AFFECTED AREA THAT ARE LIKELY TO ENSUE IF THE ADJUSTMENT IS NOT MADE

Cape Fear Valley conservatively identified 178 distinct patients for SRS treatments based on its current population base and projects that at least 250 patients will need SRS by 2011. Area 18 providers cannot replace an existing linear accelerator with a CyberKnife unit, because all existing units are already fully utilized performing EBRT. Therefore, these patients will lack access to CyberKnife technology unless they receive services from one of the three currently approved CyberKnife providers. The closest of these providers is Chapel Hill, which is two hours or more away from much of Area 18. Given the high demand anticipated by the new service at UNC there is no assurance that Area 18 residents will have access to this equipment even if they are able to drive to Chapel Hill. Patients in southeastern North Carolina do not have practical or convenient access to SRS/SRT. Without this critical choice,

patients may choose less optimal treatments (if there are choices), receive no treatment at all, or die.

A STATEMENT OF ALTERNATIVES TO THE PROPOSED ADJUSTMENT THAT WERE CONSIDERED AND FOUND NOT FEASIBLE

Cape Fear Valley has explored maintaining the status quo, which means that Area 18 will not have access to a SRS/SRT program. In fact, currently a SRS/SRT program is not available anywhere in Southeastern North Carolina (HSA V). Maintaining the status quo is not an option given the need as described above.

The second alternative we explored is replacing an existing linear accelerator with a CyberKnife dedicated to SRS/SRT. As described above, SRS/SRT is not an alternative for patients who receive external beam treatments. Rather, SRS/SRT represents a population of patients that generally have inoperable tumors, are not surgical candidates, have received maximum external beam treatments to an area, or choose SRS/SRT rather than surgery. Therefore, replacing an existing linear accelerator with a CyberKnife is only a valid option when the accelerator is not being fully utilized. Since this is not the case in Area 18, replacement is not an option.

EVIDENCE THAT HEALTH SERVICE DEVELOPMENT PERMITTED BY THE PROPOSED ADJUSTMENT WOULD NOT RESULT IN UNNECESSARY DUPLICATION OF HEALTH RESOURCES IN THE AREA.

Other CyberKnife approved or operating units are located in Asheville NC (six hours distance from Fayetteville), Concord, NC (three hours distance) and Chapel Hill (two hours distance). In fact, there are no SRS services or equipment in southeastern North Carolina. CyberKnife units are unique to other SRS/SRT technologies because it is the only system that can clinically ablate tumors anywhere in the body, without immobilization, and with sub-milliliter accuracy. Almost all other forms of SRS/SRT are mainly limited to intracranial SRS/SRT treatments. CyberKnife represents a phenomenal breakthrough in SRS/SRT technology that will undoubtedly raise the bar in SRS/SRT treatment delivery.

PETITIONERS SHOULD ASSUME THE SAME SERVICE AREA DEFINITIONS AS GIVEN IN THE PROGRAM CHAPTERS OF THE PROPOSED SMFP.

Area 18 was assumed for service area purposes for this petition.

OTHER RECOMMENDATIONS

Stereotactic Radiosurgery and Stereotactic Radiotherapy are unique and separate from external beam radiation therapy. As such, these procedures and the dedicated equipment used to deliver these treatments should be consistently reported and accounted for accurately in the inventory: (1) the "GammaKnife" heading would be more accurately changed to "Stereotactic Radiosurgery and Stereotactic Radiotherapy". The current methodology of reporting all types of SRS/SRT under the GammaKnife heading is inaccurate and misleading; (2), the Facility Inventory-Service Volume heading should contain the type of SRS/SRT equipment, either dedicated SRS/SRT unit or multi-functional linac used and the SRS/SRT procedure count produced from that equipment; and (3), need determination methodologies for SRS/SRT dedicated units like GammaKnife and CyberKnife, need to be developed that include specific criteria based on population, utilization, and location to provide the best patient access for these services throughout the state.

LETTERS OF SUPPORT

Attached are letters received to date supporting the need for an adjustment to the State Medical Facilities Plan to add the need for a CyberKnife Stereotactic Radiosurgery System in Area 18.

SOUTHEASTERN RADIATION ONCOLOGY

5 July 2007

Mr. Tom Elkins
Medical Facilities Planning Section
Division of Facilities Services
2714 Mail Service Center
Raleigh, NC 27699-2714

Re: Special need determination for CyberKnife, Cape Fear Valley Health System

Dear Mr. Elkins:

For the past 25 years, the Cancer Center at Cape Fear Valley has been caring for the people of southeastern North Carolina. Our commitment has been providing optimal state of the art treatment at Home and having the capacity to take care of every one who needs our services. We believe we offer the most comprehensive program in our region. We now have four fully utilized linear accelerators, three at Cape Fear Valley Health System and one at our recently opened facility in northern Cumberland County, Health Pavilion North. We also have a contract to manage the Radiation Oncology Division of Gibson Cancer Center of Southeastern Regional Medical Center in Lumberton. Therefore, we are directly involved in the care of patients from a large part of southeastern North Carolina from the Research Triangle down to Wilmington.

Our patients' access to the latest and best technology has rivaled that of our neighboring university hospitals. We now offer three dimensional conformal radiation therapy, intensity modulated radiation therapy and image guided radiation therapy. We have an extensive brachytherapy program that includes prostate implants and high dose rate therapy for gynecologic malignancies and partial breast irradiation, i.e. MammoSite.

Access to the latest technology is important but we also offer services that address the mind, body and soul of our patients both during and after treatment. Our Oasis Complementary Medicine Program includes six different support groups for patients and their families, nutritional classes, Healing Touch, Tai Chi, Reflexology, Massage Therapy and Look Good Feel Better.

While we are constantly refining and updating our existing programs we also have an on going obligation to evaluate new treatments that should be available to our patients and that will be future benchmarks for a comprehensive community cancer center. We therefore previously submitted a proposal to obtain a Certificate of Need to develop a stereotactic radiosurgery program based on the CyberKnife Radiosurgery system. Before doing so we carefully analyzed the needs of the patients we serve, our ability to meet

J. Hugh Bryan, M.D.
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Cape Fear Valley Medical Center

those needs and the potential impact of this service on our existing program as well as the other programs in our area. We conferred with two representatives of the CON Division Facility Services regarding our intent prior to filing our application and we were led to believe that our application was appropriate. We feel that our subsequent proposal fully satisfied the rules and guidelines that we were led to believe existed at that time for major medical equipment. Furthermore, we believe that our application was denied based on the faulty assumption that a CyberKnife is a traditional linear accelerator. This would be tantamount to categorizing a GammaKnife as a cobalt machine.

Stereotactic radiosurgery depends upon exquisite high resolution imaging of the target (lesion/tumor) and the surrounding normal structures and the ability to deliver a very high dose of radiation to that target with sub-millimeter accuracy using a large number of small cross-fired radiation beams as a non-invasive surgical knife. This use of radiation is aptly termed "surgery without a knife".

Patients who are candidates for radiosurgery are a unique group and most often simply have no other alternative. They are often medically inoperable due to pre-existing conditions such as chronic lung disease, coronary artery disease, etc. The tumor may be surgically unresectable. They may have recurrent tumor within a previously irradiated area.

In other words, these are patients that you otherwise just could not treat in any other way. Treating them, therefore, does not decrease the workload on your existing linear accelerators. As a matter of fact, statistics from departments with a CyberKnife show an increase in the number of patients receiving traditional radiation therapy. This phenomenon is generally attributed to an enhanced departmental image which leads to an increased number of referrals.

The GammaKnife was the first instrument developed for radiosurgery. This machine focuses 201 beams of gamma radiation from 201 separate cobalt sources on a precise target. It is limited to neurosurgical/brain-only applications and requires immobilization with a rigid head frame that is attached to the skull with four pins. Treatment planning may require several hours thereafter and the head frame must remain in place. Therefore, due to the complexity of the set-up and patient tolerance, GammaKnife treatment is limited to a single fraction.

The foundation of radiation oncology departments is the traditional linear accelerator. Recent advances in linear accelerator technology include intensity modulated radiation therapy (IMRT) and image guided radiation therapy (IGRT). These techniques allow for more precise irradiation of the intended target while limiting the dose to adjacent critical structures. Several machines, e.g., Varian's Trilogy, Elekta's Synergy and BrainLab's Novalis, are designed to be "all purpose" units capable of standard treatment as well as intracranial and extracranial stereotactic radiosurgery. However, recent surveys including an analysis of these machines in our own State shows that they are underutilized for this purpose.

We considered these all-purpose linear accelerators as well as Tomotherapy when we made our choice and after considerable consultation and thoughtful analysis we are absolutely convinced that none of them performs intracranial and extracranial stereotactic radiosurgery with the precision, elegance and efficiency of CyberKnife.

The CyberKnife was developed exclusively for stereotactic radiosurgery. The CyberKnife includes a light, compact 6MeV linear accelerator mounted on a precise computer driven robotic arm. Patients are treated lying on a couch while the robotic arm moves the small linear accelerator around then. The machine is capable of delivering beams as small as 5 mm from 1600 different positions. It can therefore deliver a homogenous dose to a target of any shape with sub-millimeter accuracy by superimposing a very large number of suitably angled and weighted small beams. Uniquely, the position of the target is continuously monitored throughout treatment and the robot trajectory is appropriately adjusted to account for any patient movement. CyberKnife can therefore treat lesions that move with respiration. The patients can be treated without uncomfortable body or head frames and treatment can be fractionated, i.e., one to five treatments instead of only one, and this may be beneficial when the target closely approximates a critical radiosensitive structure.

The CyberKnife can be used to treat a wide variety of medical conditions including cancers, benign tumors, and lesions anywhere in the body and now at least 50% of treatments are extracranial. CyberKnife radiosurgery can be used for benign intracranial lesions such as acoustic neuroma, meningioma, pituitary adenoma, arteriovenous malformation and trigeminal neuralgia. It often provides superior palliation in patients with brain metastases. Patients with early stage cancers of the lung or prostate can achieve results comparable to surgery if they wish to avoid an operation or if they are medically unfit for an invasive procedure. Unprecedented local control can be achieved in certain inoperable tumors, e.g. pancreas. CyberKnife radiosurgery can provide rapid durable palliation in patients with bone, spine and liver metastases. It may be the only alternative for patients who have suffered local recurrence in spite of previous surgery and/or radiation therapy. In many instances, CyberKnife allows treatment for patients who are simply untreatable in the past.

A CyberKnife is no more a traditional linear accelerator than a GammaKnife is a cobalt machine and I fear that this misconception, if it persists, will deny our patients access to this new and exciting technology. As noted, a radiosurgery program attracts new patients that otherwise would not be treated and therefore, at least initially has no effect on the utilization of existing linear accelerators. As noted above, it may actually increase utilization in the future. Therefore, it seems unreasonable for an institution who can demonstrate the need for and the means to provide stereotactic radiosurgery to have to wait until there is an allocation for an accelerator in their area. Similarly, it also seems unreasonable to require an institution with fully utilized linear accelerators to decommission and relinquish the CON for one of their machines in order to acquire a stereotactic radiosurgery system in a timely fashion since this would inevitably result in over utilization of their remaining machines. This scenario could be a nightmare for all of us!

We believe that our application for CyberKnife demonstrates a need for stereotactic radiosurgery in our area as well as our ability to provide this service in an optimal fashion. While there are other methods of delivering stereotactic radiosurgery, we feel that CyberKnife is unique and the best solution for our patient population. Different institutions have different needs and may decide that GammaKnife, Tomotherapy or a modified all-purpose accelerator is best for them. We would not presume to select which technology is best for them or interfere with their ability to obtain a proper CON.

In summary, we believe that dedicated stereotactic radiosurgery systems such as CyberKnife should be placed in a special category and not considered replacement for standard linear accelerators. This would facilitate the orderly, controlled growth of stereotactic radiosurgery in North Carolina and ensure that our patients continue to have optimal access to oncology services.

Sincerely,

J. Hugh Bryan, MD
Medical Director
Radiation Oncology

SINAI HOSPITAL
a LifeBridge Health center

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2401 West Belvedere Avenue
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June 25, 2007

Mr. Tom Elkins
Medical Facilities Planning Section
Division of Facility Services
2714 Mail Service Center
Raleigh NC 27699-2714

RE: Special Need Determination for CyberKnife, Cape Fear Valley Health System

Dear Mr. Elkins:

I am writing to you in my capacity as chief of Radiation Oncology at Sinai Hospital of Baltimore. We provide standard Radiation Oncology services, both 2-dimensional Radiation Therapy and its immediate successor, 3-dimensional conformal radiation therapy (3D-CRT), and the two subsequent upgrades, Intensity Modulated Radiation Therapy (IMRT), and Image-Guided Radiation Therapy (IGRT). In April of 2003 we added Stereotactic Radiosurgery (SRS) to our practice in the form of the CyberKnife. Since then we have treated over 1000 with the CyberKnife, and in January of this year we started operations with our second CyberKnife, so great has the demand for it been. Unlike the aforementioned modes of pure Radiation Oncology, SRS is really a hybrid of radiation and surgery. Here, multiple pinpoint precise individual beams of irradiation are directed to a target, delivering doses far in excess of what can be done with any of the available modalities of standard irradiation, with the aim of ablating the tumor. SRS is truly "surgery without the scalpel"—it takes its lineage from the traditional neurosurgical/brain-only applications as provided by Gamma Knife, but with the crucial differences that it does not require that the patient be rigidly immobilized, and that it can treat lesions anywhere in the body. At our center we have already treated over 60 cases of medically inoperable lung cancers, and we presently have the largest series of stereotactically treated unresectable pancreatic cancers in the world!

Almost all Radiation Oncology departments today have traditional linear accelerators with IMRT/IGRT capacity, which allow for better treatment than older methods of therapy for cases where the tumor exists close to critical structures. But these systems do not and can not do true radiosurgery.

Stereotactic radiosurgery differs from these other techniques in several crucial ways:

1. Only the gross tumor is treated, with no attempt to treat the surrounding soft tissues and/or the draining lymph nodes, which may or may not contain microscopic tumor.

2. Little or no margin around the tumor is added to allow for day-to-day set-up variations or uncertainties, even without rigid immobilization, because,....

3. The system "knows" in real time where the patient and the tumor are located in all three dimensions and adjusts accordingly. Unlike the situation with IGRT, wherein imaging allows for precise day-to-day setup **before the beam is turned on**, this is true image guidance and artificial intelligence technology. Incredibly high doses of irradiation are delivered with pinpoint precision even to tumors that constantly move with respiration, in patients who move randomly and intermittently, with a margin of error of at most 1-2 millimeters!

4. Courses of treatment are administered over one to five fractions, not over several weeks, as is the case with standard Radiation Oncology.

SRS is not an alternative to radiation but to surgery. The paradigm here is that is that it is the surgeon who determines that whereas ideally the patient would be taken to the O.R., surgery is precluded because **the patient is medically inoperable** (e.g. severe COPD or coronary artery disease), and/or **the tumor is surgically unresectable** (e.g. it is encasing major vessels, or the region has already undergone maximum prior surgery or radiation). We recently looked back at all our CyberKnife cases, and found that virtually **none** of them could be treated with the available technology of pure Radiation Oncology (2D, 3D, IMRT or IGRT).

I would respectfully submit that dedicated SRS systems such as the CyberKnife should be separately accounted for in North Carolina for radiation therapy systems. These units are **not** replacements for standard linear accelerators, but rather, an entirely new modality, a hybrid of radiation and surgery, which provide

an alternative to surgery for patients who heretofore had simply run out of options.

Sincerely yours,

Mark J. Brenner, M.D., FACR
Chairman, Department of Radiation Oncology
Sinai Hospital of Baltimore
MJB/jmb

Southwest Radiation Oncology

June 23, 2007

Mr. Tom Elkins
Medical Facilities Planning Section
Division of Facility Services
2714 Mail Service Center
Raleigh NC 27699-2714

RE: Special Need Determination for CyberKnife, Cape Fear Valley Health System

Southwest Radiation Oncology is an Oklahoma provider of Radiation Oncology services. These services include devices that can provide radiation therapy (RT), Intensity Modulated Radiation Therapy (IMRT), and Image-Guided Radiation Therapy (IGRT). In 2003, we investigated adding a Stereotactic Radiosurgery (SRS) Program to our practice. Our research indicated that SRS has evolved from the traditional neurosurgical/brain-only applications as provided by Gamma Knife or similar devices into a treatment option for lesions anywhere in the body. Before adding SRS to our practice we investigated thoroughly the impact an SRS program would have on our existing radiation therapy programs, our patients, and our community.

Many centers have traditional linear accelerators that used advanced technology for enhanced patient treatment, such as intensity modulated radiation therapy and/or image guided radiation therapy. Although these allow for better treatment than older methods of therapy for cases where the tumor exists close to critical structures, they are technologically and clinically distinct from radiosurgery. Stereotactic radiosurgery (SRS) differs from these other techniques in several ways:

1. Patients are treated in 1-5 fractions, not several weeks.
2. The identifiable tumor is treated, not areas at risk.
3. Little or no margin around the tumor is added to account for set-up uncertainties.
4. Image guidance is used daily.

SRS is generally used in two situations:

1. The patient would ordinarily be treated with surgery, but is not medically fit for such surgical intervention.
2. The problem is one for which surgery is impossible or inadvisable and standard radiation techniques have a high risk of resulting in significant injury.

SRS can sometimes be performed by traditional linear accelerators using special modifications, but is probably best performed by dedicated systems such as the CyberKnife. The CyberKnife also has the advantage of allowing motion tracking for tumors that move with respiration, and is the only system capable of such tracking.

For all these reasons, dedicated SRS systems such as the CyberKnife should separately accounted for in the planning of the state of North Carolina for radiation therapy systems. These units are not replacements for standard linear accelerators. It would be anticipated that the number of such systems would be far lower than the number of standard accelerators, but additional linear accelerators will not replace these systems.

Sincerely,

Clinton A. Medbery, III, M.D.
President
Southwest Radiation Oncology

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Main Number: 405.272.7311
Fax Number: 405.272.6962
After Hrs. Number: 405.272.7311

CUMBERLAND COUNTY

BOARD OF COMMISSIONERS
5th Floor, New Courthouse • P.O. Box 1829 • Fayetteville, North Carolina 28302-1829
910 678-7771 • Fax: 910 678-7770

July 27, 2007

Tom Elkins
Medical Facilities Planning Section
The Division of Health Service Regulation
2714 Mail Service Center
Raleigh, NC 27699-2714.

Dear Mr. Elkins:

I am writing to support Cape Fear Valley Health System's request in petitioning for a need adjustment to the State Medical Facilities Plan (SMFP) to add the need for a CyberKnife Stereotactic Radiosurgery System in Area 18. I feel that the best possible healthcare and health technology should be available for our citizens. I believe that if Cape Fear Valley Health System replaces one of its fully-utilized linear accelerators, it will not best serve patients and that area residents should have access to leading edge technologies accessible to other North Carolina residents.

I am convinced that Area 18 is truly in a unique position relative to its large population and its inability to replace a highly utilized linear accelerator with CyberKnife equipment for stereotactic radiosurgery. It doesn't seem fair that areas with fewer capacity constraints should have better access to SRS/SRT services than other areas in North Carolina. For Cape Fear Valley, along with the residents of Area 18, to possibly not be able to gain access to CyberKnife technology considering a) the current linear accelerator methodology, b) the CON section's interpretation that the SMFP demonstrate a need for an accelerator before CyberKnife equipment is acquired, and c) the current utilization rate of Area 18's linear accelerators, in my opinion is unreasonable.

Your consideration to this request is appreciated.

Sincerely,

Ed Melvin

Ed Melvin
Commissioner

CUMBERLAND COUNTY

BOARD OF COMMISSIONERS
5th Floor, New Courthouse • PO Box 1829 • Fayetteville, North Carolina 28302-1829
(910) 678-7771 • Fax: (910) 678-7770

July 27, 2007

Tom Elkins
Medical Facilities Planning Section
The Division of Health Service Regulation
2714 Mail Service Center
Raleigh, NC 27699-2714

Dear Mr. Elkins:

Please accept this letter as my support of Cape Fear Valley Health System's request in petitioning for a need adjustment to the State Medical Facilities Plan (SMFP) to add the need for a CyberKnife Stereotactic Radiosurgery System in Area 18. The health system is convinced that replacing one of its fully-utilized linear accelerators will not best serve patients and that area residents should have access to leading edge technologies accessible to other North Carolina residents.

For Cape Fear Valley, along with the residents of Area 18, to possibly not be able to gain access to CyberKnife technology considering a) the current linear accelerator methodology, b) the CON section's interpretation that the SMFP demonstrate a need for an accelerator before CyberKnife equipment is acquired, and c) the current utilization rate of Area 18's linear accelerators, in my opinion is unreasonable. Moreover, when need is identified in future SMFPs, Cape Fear Valley or other Area 18 providers may be compelled to add an EBRT linear accelerator given the capacity constraints (surely to be created if one of the current accelerators is replaced). I am convinced that Area 18 is truly in a unique position relative to its large population and its inability to replace a highly utilized linear accelerator with CyberKnife equipment for stereotactic radiosurgery.

I am hopeful that you will be convinced by the reasonable rationale submitted by Cape Fear Valley Health System that a need adjustment to the State Medical Facilities Plan (SMFP) to add the need for a CyberKnife Stereotactic Radiosurgery System in Area 18 is warranted and has

merit. As a long time resident and member of the Cumberland County Board of Commissioners, I want the best possible healthcare and health technology available for me as well as the citizens I represent. Thank you for your consideration of this request.

Sincerely,

Billy R. King

Billy R. King
Commissioner

/mc

CUMBERLAND COUNTY

BOARD OF COMMISSIONERS
5th Floor, New Courthouse • PO Box 1829 • Fayetteville, North Carolina 28302-1829
(910) 678-7771 • Fax: (910) 678-7770

July 27, 2007

Tom Elkins
Medical Facilities Planning Section
The Division of Health Service Regulation
2714 Mail Service Center
Raleigh, NC 27699-2714

Dear Mr. Elkins:

I support Cape Fear Valley Health System's request in petitioning for a need adjustment to the State Medical Facilities Plan (SMFP) to add the need for a CyberKnife Stereotactic Radiosurgery System in Area 18. I feel that the best possible healthcare and health technology should be available for our citizens.

For Cape Fear Valley, along with the residents of Area 18, to possibly not be able to gain access to CyberKnife technology considering a) the current linear accelerator methodology, b) the CON section's interpretation that the SMFP demonstrate a need for an accelerator before CyberKnife equipment is acquired, and c) the current utilization rate of Area 18's linear accelerators, in my opinion is unreasonable. Moreover, when need is identified in future SMFPs, Cape Fear Valley or other Area 18 providers may be compelled to add an EBRT linear accelerator given the capacity constraints (surely to be created if one of the current accelerators is replaced).

I would appreciate your consideration in granting the request for the need adjustment to the State Medical Facilities Plan (SMFP) to add the need for a CyberKnife Stereotactic Radiosurgery System in Area 18.

Sincerely,

Jeannette Council

Jeannette Council
Commissioner

/ mc

JAMES E. MARTIN
County Manager

JUANITA PILGRIM
Deputy County Manager

CLIFF SPILLER
Assistant County Manager

AMY H. CANNON
Assistant County Manager

CUMBERLAND COUNTY

OFFICE OF THE COUNTY MANAGER
5th Floor, New Courthouse • PO Box 1829 • Suite 512 • Fayetteville, North Carolina 28302-1829
910-678-7723 • 910-678-7726 • Fax: 910-678-7717

July 27, 2007

Tom Elkins
Medical Facilities Planning Section
The Division of Health Service Regulation
2714 Mail Service Center
Raleigh, NC 27699-2714

Dear Mr. Elkins:

Please accept this letter in support of Cape Fear Valley Health System's request in petitioning for a need adjustment to the State Medical Facilities Plan (SMFP) to add the need for a CyberKnife Stereotactic Radiosurgery System in Area 18. I believe that if Cape Fear Valley Health System replaces one of its fully-utilized linear accelerators, it will not best serve patients and that area residents should have access to leading edge technologies accessible to other North Carolina residents. I feel that the best possible healthcare and health technology should be available for our citizens.

I am convinced that Area 18 is truly in a unique position relative to its large population and its inability to replace a highly utilized linear accelerator with CyberKnife equipment for stereotactic radiosurgery. It doesn't seem fair that areas with fewer capacity constraints should have better access to SRS/SRT services than other areas in North Carolina. For Cape Fear Valley, along with the residents of Area 18, to possibly not be able to gain access to CyberKnife technology considering a) the current linear accelerator methodology, b) the CON section's interpretation that the SMFP demonstrate a need for an accelerator before CyberKnife equipment is acquired, and c) the current utilization rate of Area 18's linear accelerators, in my opinion is unreasonable. Moreover, when need is identified in future SMFPs, Cape Fear Valley or other Area 18 providers may be compelled to add an EBRT linear accelerator given the capacity constraints (surely to be created if one of the current accelerators is replaced).

I would appreciate your favorable consideration of the request for the need adjustment to the State Medical Facilities Plan (SMFP) to add the need for a CyberKnife Stereotactic Radiosurgery System in Area 18.

Sincerely,

James Martin
County Manager

CUMBERLAND COUNTY

BOARD OF COMMISSIONERS
5th Floor, New Courthouse • P.O. Box 1829 • Fayetteville, North Carolina 28302-1829
910.678-7771 • Fax: 910.678-7770

July 27, 2007

Tom Elkins
Medical Facilities Planning Section
The Division of Health Service Regulation
2714 Mail Service Center
Raleigh, NC 27699-2714

Dear Mr. Elkins:

This letter is written in support of Cape Fear Valley Health System's request in petitioning for a need adjustment to the State Medical Facilities Plan (SMFP) to add the need for a CyberKnife Stereotactic Radiosurgery System in Area 18. I agree with Cape Fear Valley Health System that replacing one of its fully-utilized linear accelerators will not best serve patients and that area residents should have access to leading edge technologies accessible to other North Carolina residents. As a long-time resident and member of the Cumberland County Board of Commissioners, I want the best possible healthcare and health technology available for the citizens of Cumberland County.

It doesn't seem fair that areas with fewer capacity constraints should have better access to SRS/SRT services than other areas in North Carolina. For Cape Fear Valley along with the residents of Area 18 to possibly not be able to gain access to CyberKnife technology considering a) the current linear accelerator methodology, b) the CON section's interpretation that the SMFP demonstrate a need for an accelerator before CyberKnife equipment is acquired, and c) the current utilization rate of Area 18's linear accelerators, in my opinion is unreasonable. Moreover, when need is identified in future SMFPs, Cape Fear Valley or other Area 18 providers may be compelled to add an EBRT linear accelerator given the capacity constraints (surely to be created if one of the current accelerators is replaced). I am convinced that Area 18 is truly in a unique position relative to its large population and its inability to replace a highly utilized linear accelerator with CyberKnife equipment for stereotactic radiosurgery.

I am hopeful that you will agree that a need adjustment to the State Medical Facilities Plan (SMFP) to add the need for a CyberKnife Stereotactic Radiosurgery System in Area 18 is warranted and has merit. Thank you for your consideration of this request.

Sincerely,

J. Breeden Blackwell

J. Breeden Blackwell
Vice-Chairman

/mc

CUMBERLAND COUNTY

BOARD OF COMMISSIONERS
5th Floor, New Courthouse • P.O. Box 1829 • Fayetteville, North Carolina 28302-1829
910 678-7771 • Fax: 910 678-7770

July 27, 2007

Tom Elkins
Medical Facilities Planning Section
The Division of Health Service Regulation
2714 Mail Service Center
Raleigh, NC 27699-2714

Dear Mr. Elkins:

Please know that I am in support of Cape Fear Valley Health System's request in petitioning for a need adjustment to the State Medical Facilities Plan (SMFP) to add the need for a CyberKnife Stereotactic Radiosurgery System in Area 18. The health system is convinced that replacing one of its fully-utilized linear accelerators will not best serve patients and that area residents should have access to leading edge technologies accessible to other North Carolina residents. As a long time resident and member of the Cumberland County Board of Commissioners, I want the best possible healthcare and health technology available for me as well as the citizens I represent.

For Cape Fear Valley, along with the residents of Area 18, to possibly not be able to gain access to CyberKnife technology considering a) the current linear accelerator methodology, b) the CON section's interpretation that the SMFP demonstrate a need for an accelerator before CyberKnife equipment is acquired, and c) the current utilization rate of Area 18's linear accelerators, in my opinion is unreasonable. Moreover, when need is identified in future SMFPs, Cape Fear Valley or other Area 18 providers may be compelled to add an EBRT linear accelerator given the capacity constraints (surely to be created if one of the current accelerators is replaced). I am convinced that Area 18 is truly in a unique position relative to its large population and its inability to replace a highly utilized linear accelerator with CyberKnife equipment for stereotactic radiosurgery. It doesn't seem fair that areas with fewer capacity constraints should have better access to SRS/SRT services than other areas in North Carolina.

I am hopeful that you will be convinced by the reasonable rationale submitted by Cape Fear Valley Health System that a need adjustment to the State Medical Facilities Plan (SMFP) to add

the need for a CyberKnife Stereotactic Radiosurgery System in Area 18 is warranted and has merit. Thank you for your consideration of my and their request.

Sincerely,

Kenneth S. Edge
Chairman

/mc

Health & Healing
2623 Westchester Drive
Fayetteville, NC 28303-5227

July 31, 2007

Mr. Tom Elkins
Medical Facilities Planning Section
Division of Health Service Regulation
2714 Mail Service Center
Raleigh, NC 27699-2714

Dear Mr. Elkins:

I am writing on behalf of Cape Fear Valley Health System (CFVHS) to request your support in adjusting the definition of "need" for the system. As a retired MCH nursing consultant with the Division of Health Services, I support the need for your agency to oversee allocations of "high- dollar" medical equipment in our State. In my former life, I found that the Cumberland-Bladen-Robeson-Sampson geographic area was always trying to play catch-up with the rest of North Carolina in obtaining the equipment needed to provide appropriate services to the population in three of the geographically largest counties of our State. Because we are still trying to catch up on equipment and because of the geographic size of the area, we needed the Linear Accelerator placed at the Health Pavilion North campus of CFVHS to meet the needs of our citizens.

Today, we are also in a new era for Cape Fear Valley Health System. In addition to the more routine services found in a large medical center, we are ready to provide cutting-edge technology. We are also attempting to reach out to the surrounding counties to meet the needs of the medically underserved population in this large region as well as that of Cumberland County. In addition, Ft. Bragg is one of the bases that is in the process of enlarging under the Base Realignment and Closure (BRAC) recommendations; and, Ft. Bragg is a base of choice for soldiers who have exceptional family member needs. Our neurosurgeons serve both soldiers and their dependents. It is anticipated that we may also see the need for CyberKnife Stereotactic Radiosurgery in this younger population.

Last November we requested approval for the CyberKnife. Please see my attached letter of support dated 11/09/06. Nothing has changed, except my friend, the cancer patient who could have used this type of surgery, has died. We still have the support of the multiple physician practices and people in need. While we still need and utilize the Linear Accelerator when it is appropriate, we also have a need and responsibility to provide cutting-edge technology to the population of Southeastern North Carolina which the CyberKnife Stereotactic Radiosurgery system will provide. While this is a large geographic area, Fayetteville is easily accessible to all major areas in the surrounding

counties. We hope you will consider the placement of the CyberKnife at Cape Fear Valley Health System to meet your objectives: to promote and encourage cost-effective quality health care services and to expand the health care services to an area that is medically underserved. With your support, we, the trustees of Cape Fear Valley Health System, are willing to take on this responsibility.

Thank you in advance for expanding your consideration to enable us to meet the needs of the population of southeastern North Carolina.

Sincerely,

Mary Buie

Mary Buie, RN, MPH, Secretary/Treasurer
Cape Fear Valley Health System Board of Trustees

Cc: Linda Clark
Joyce Korzen

G

John R. Griffin, Jr.
2481 Themesford Road
Fayetteville, NC 28311
****

July 31, 2007

Tom Elkins
Medical Facilities Planning Section
The Division of Health Service Regulation
2714 Mail Service Center
Raleigh, NC 27699-2714

Dear Mr. Elkins:

Please know that I am in support of Cape Fear Valley Health System's request in petitioning for a need adjustment to the State Medical Facilities Plan (SMFP) to add the need for a CyberKnife Stereotactic Radiosurgery System in Area 18. The health system is convinced that replacing one of its fully-utilized linear accelerators will not best serve patients and that area residents should have access to leading edge technologies accessible to other North Carolina residents. As a long time resident of Cumberland County, former Superintendent of the Cumberland County School System and a current member of the Board of Trustees, I know that we need the best possible healthcare and health technology available for the citizens of Cumberland County and this region.

For Cape Fear Valley along with the residents of Area 18 to possibly not be able to gain access to CyberKnife technology considering a) the current linear accelerator methodology, b) the CON section's interpretation that the SMFP demonstrate a need for an accelerator before CyberKnife equipment is acquired, and c) the current utilization rate of Area 18's linear accelerators, in my opinion is unreasonable. Moreover, when need is identified in future SMFPs, Cape Fear Valley or other Area 18 providers may be compelled to add an EBRT linear accelerator given the capacity constraints (surely to be created if one of the current accelerators is replaced). I am convinced that Area 18 is truly in a unique position relative to its large population and its inability to replace a highly utilized linear accelerator with CyberKnife equipment for stereotactic radiosurgery. It doesn't seem fair that areas with fewer capacity constraints should have better access to SRS/SRT services than other areas in North Carolina.

Hopefully, you will be convinced by the reasonable rationale submitted by Cape Fear Valley Health System that a need adjustment to the State Medical Facilities Plan (SMFP) to add the need for a CyberKnife Stereotactic Radiosurgery System in Area 18 is warranted and has merit. Thank you for your sincere consideration of Cape Fear Valley's request.

Sincerely,

John R. Griffin, Jr.
First Vice Chairman, Board of Trustees

BCH
BLADEN COUNTY HOSPITAL

July 31, 2007

Mr. Tom Elkins, Medical Facilities Planning Section
Division of Health Service Regulation
2714 Mail Service Center
Raleigh, NC 27699-2714

Dear Mr. Elkins,

On behalf of Bladen County Hospital and the citizens of Bladen County, I am writing to support the application submitted by Cape Fear Valley Health System for an additional linear acceleration dedicated to Cyberknife Technology.

It is our understanding that this minimally invasive technology is rapidly becoming standard of practice throughout the state for the treatment of cancer, and we support the efforts of Cape Fear Valley Health System to bring Cyberknife Stereotactic Radiosurgery to the citizens of Southeastern North Carolina.

This technology requires the dedication of a linear accelerator and we believe that the advancements in medicine should be considered in adjusting need determination for linear accelerators in the State's Medical Facility Plan. Recognizing that the regional demand for the existing linear accelerators exceeds capacity further compels us to support this request.

In summary, Bladen County Hospital, as a primary care provider in a contiguous county, supports Cape Fear Valley Health System's request to appropriately adjust the need determination as stated in the State Medical Facility Plan to recognize the requirements for Cyberknife Stereotactic Radiosurgery in area 18.

Respectfully submitted,

David J. Masterson, CEO
Bladen County Hospital

Cc: Lynda Clark, VP Professional Services
CFVHS

North Carolina General Assembly
House of Representatives
Legislative Building
Raleigh 27601-1096

Former / Retired
REPRESENTATIVE JOHN W. "BILL" HURLEY
18TH DISTRICT
OFFICE ADDRESS 2215 LEGISLATIVE BUILDING
RALEIGH, NC 27601-1096
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(910) 868-4078
BUS. ADDRESS PO BOX 714
FAYETTEVILLE, NC 28302
(910) 483-6210

COMMITTEES
INSURANCE, CHAIR
MILITARY, VETERANS & INDIAN AFFAIRS, CHAIR
CONGRESSIONAL REDISTRICTING
ETHICS
FINANCE
LOCAL GOVERNMENT II
PUBLIC UTILITIES

July 31, 2007

Mr. Tom Elkins
Medical Facilities Planning Section
The Division of Health Service Regulation
2714 Mail Service Center
Raleigh, NC 27699-2714

Dear Mr. Elkins:

Recently, I received information from Cape Fear Valley Medical Health System (CFVHS) advising that a request for a CyberKnife Stereotactic Radiosurgery System was denied by your section.

I would like to request that due to the significance of the geographic location and the population in our region you reverse this decision, make an adjustment to need determination, and grant this certification of need for the CyberKnife Stereotactic Radiosurgery System. Our military base alone will increase by 2,100 people before the year 2010. As you know, our area is still the predominate metro-hub in southeastern North Carolina, and I feel the requested system would be of great value to the citizens of Cumberland and surrounding counties.

Your consideration of this request is appreciated, and if you have any questions or I can be of further service, please contact me.

Sincerely,

John W. "Bill" Hurley

JWHm

Top of Document

Technology and Equipment Committee Meeting

August 29, 2007

Radiation Oncology Services - Linear Accelerators

Comments Related To

Linac Petition-2: Cape Fear Valley Health System

COUNTY *of* CUMBERLAND

Board of County Commissioners

August 2, 2007

Mr. Tom Elkins
Medical Facilities Planning Section
Division of Health Service Regulation
2714 Mail Service Center
Raleigh, NC 27699-2714

Dear Mr. Elkins,

I am writing this letter on behalf of Cape Fear Valley Health System's request for an adjustment to the need determination for the development of a CyberKnife Stereotactic Radiosurgery system in the 2008 Sate Medical Facilities plan (SMFP) in linear accelerator area 18 (Area 18).

As an Otolaryngologist and a member of the Cumberland County Board of Commissioners, I strongly support this request for the requested adjustment of the SMFP. It is my understanding that the previous application for the CyberKnife was denied because the population per accelerator in Area 18 did not exceed 120,000 persons and only 12% of patients treated here resided outside Area 18. There are two issues here that must be considered. As you may very well know, with the recent base realignment, there will be substantial growth in the Cumberland County and surrounding region over the next 3-4 years. As a county commissioner, I have been briefed as county commissioners that up to 40,000 people will be moving into Cumberland County and surrounding counties because of the expected growth of Fort Bragg. There will, therefore, be increased need for this type of treatment for the military and their dependents as well. In addition, there is an ever increasing number of specialists in Cumberland County and surrounding areas who will be referring patients for this technology. I strongly believe in my own specialty and in others that this type of new technology will be a strong draw for patients to have access to and utilization of this new technology.

It is also impractical for Cape Fear Valley to replace an existing linear accelerator with the CyberKnife technology. Our utilization of our current linear accelerators already exceeds the state requirement for an additional

accelerator. By merely substituting the CyberKnife for a linear accelerator, it will delay needed radiation therapy to patients requiring that specific methodology rather than the treatment offered by the CyberKnife technology.

Finally, I am aware that CyberKnife services are available in Asheville and in Concord. In addition, UNC and East Carolina University have either been approved or have applied for this technology. For many years, residents of Cumberland and surrounding counties have been delayed in obtaining needed approvals for services to be provided to our residents. This is a low wealth area and our patients deserve and need access to the latest technology in the treatment of their malignancies. It is impractical for many of these low income patients to travel to UNC or, as I believe likely, to one of the facilities in Wake County or to Duke University which will ultimately be approved. It is entirely appropriate for the SMFP to be adjusted to allow this technology to be placed centrally in southeastern North Carolina and to provide service in this area. As previously noted, Cumberland County and the Cape Fear Valley Health System will be rapidly growing and, for the first time in my 27 years here, we are beginning to see an influx of new, well-trained physicians in many specialties. Although those persons living in the triangle have had the privilege of easy access to specialty care for many years, that has not been true in Cumberland County and in southeastern North Carolina. It is time to allow Cape Fear Valley Health System to provide this needed service as soon as possible.

If I may supply additional information, please do not hesitate to contact me.

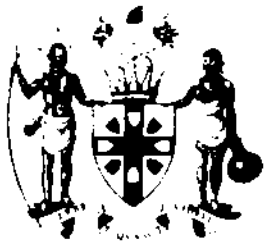
Sincerely,

John T. Henley, Jr., MD
JTH/cwc

SENATE OF NORTH CAROLINA

SENATOR TONY RAND
19TH DISTRICT

LEGISLATIVE OFFICE BUILDING
300 N. SALISBURY STREET
RALEIGH, N.C. 27603-5925
919.733.9892
919.715.8346 FAX
tonyr@ncleg.net



MAJORITY LEADER

CHAIRMAN,
RULES AND OPERATIONS OF THE SENATE
CHAIRMAN,
EMPLOYEE HOSPITAL AND MEDICAL BENEFITS
VICE CHAIRMAN,
COMMERCE

August 2, 2007

Tom Elkins
Medical Facilities Planning Section
The Division of Health Service Regulation
2714 Mail Service Center
Raleigh, NC 27699-2714

Dear Mr. Elkins:

This letter is written in support of Cape Fear Valley Health System's request for an adjustment to need determination for the development of a CyberKnife Stereotactic Radiosurgery System in the 2008 State Medical Facilities Plan (SMFP) in linear accelerator Area 18.

Cape Fear Valley Health System's linear accelerators already exceed the capacity threshold, so replacing an existing linear accelerator with a CyberKnife Stereotactic Radiosurgery System is not an option for Area 18. Area 18 has a large population of over 535,000 people. This is more than adequate to support a dedicated SRS/SRT service.

Cape Fear Valley Health System has been providing quality healthcare for the residents of Cumberland County and surrounding communities since 1956. The additional services would allow them to provide the best available technology to treat patients with devastating illnesses. I would appreciate your consideration of this request.

Very truly yours,

Anthony E. Rand

AER:jt

2014 LITHO PLACE, FAYETTEVILLE, NORTH CAROLINA 28304
BUSINESS – 910.222-8006 EXT. 245 HOME – 910.864-0550

BCH
BLADEN COUNTY HOSPITAL

DFS Health Planning
RECEIVED
AUG 04 2007
Medical Facilities
Planning Section

July 31, 2007

Mr. Tom Elkins, Medical Facilities Planning Section
Division of Health Service Regulation
2714 Mail Service Center
Raleigh, NC 27699-2714

Dear Mr. Elkins,

On behalf of Bladen County Hospital and the citizens of Bladen County, I am writing to support the application submitted by Cape Fear Valley Health System for an additional linear acceleration dedicated to Cyberknife Technology.

It is our understanding that this minimally invasive technology is rapidly becoming standard of practice throughout the state for the treatment of cancer, and we support the efforts of Cape Fear Valley Health System to bring Cyberknife Stereotactic Radiosurgery to the citizens of Southeastern North Carolina.

This technology requires the dedication of a linear accelerator and we believe that the advancements in medicine should be considered in adjusting need determination for linear accelerators in the State's Medical Facility Plan. Recognizing that the regional demand for the existing linear accelerators exceeds capacity further compels us to support this request.

In summary, Bladen County Hospital, as a primary care provider in a contiguous county, supports Cape Fear Valley Health System's request to appropriately adjust the need determination as stated in the State Medical Facility Plan to recognize the requirements for Cyberknife Stereotactic Radiosurgery in area 18.

Respectfully submitted,

David J. Masterson, CEO
Bladen County Hospital

Cc: Lynda Clark, VP Professional Services
CFVHS

Buie, Norman & Co., P.A.
CERTIFIED PUBLIC ACCOUNTANTS

2294 McGill Drive
Post Office Box 87047
Fayetteville, NC 28304-7047
www.buienorman.com

John G. Buie, Jr., CPA
Robert D. Norman, CPA
Larry L. Bass, Jr., CPA

Tel: (910) 484-0145
Fax: (910) 485-4524

Member AICPA, NCACPA

July 31, 2007

Tom Elkins
Medical Facilities Planning Section
The Division of Health Service Regulation
2714 Mail Service Center
Raleigh, NC 27699-2714.

Dear Mr. Elkins:

Cape Fear Valley Health System has submitted a request to the Division of Health Service Regulation petitioning for a need adjustment to the State Medical Facilities Plan (SMFP) to add the need for a CyberKnife Stereotactic Radiosurgery System in Area 18 and I am extremely supportive of this request. The health system is convinced that replacing one of its fully-utilized linear accelerators will not best serve patients and that area residents should have access to leading edge technologies accessible to other North Carolina residents. As a long time resident of Cumberland County and a current member of the Board of Trustees, I know that we need and are expected to provided the best possible healthcare and health technology for the citizens of Cumberland County and this region.

For the residents of Area 18 along with Cape Fear Valley to possibly not be able to gain access to CyberKnife technology considering a) the current linear accelerator methodology, b) the CON section's interpretation that the SMFP demonstrate a need for an accelerator before CyberKnife equipment is acquired, and c) the current utilization rate of Area 18's linear accelerators, in my opinion is unreasonable. Moreover, when need is identified in future SMFPs, Cape Fear Valley or other Area 18 providers may be compelled to add an EBRT linear accelerator given the capacity constraints (surely to be created if one of the current accelerators is replaced). I am certain that Area 18 is truly in a unique position relative to its large population and its inability to replace a highly utilized linear accelerator with CyberKnife equipment for stereotactic radiosurgery. It doesn't seem fair that areas with fewer capacity constraints should have better access to SRS/SRT services than other areas in North Carolina.

I am convinced that after review of the reasonable rationale submitted by Cape Fear Valley Health System that a need adjustment to the State Medical Facilities Plan (SMFP) to add the need for a CyberKnife Stereotactic Radiosurgery System in Area 18 is warranted, has merit and should be approved. Thank you for your sincere consideration of my support and Cape Fear Valley's request.

Sincerely,

John G. Buie, Jr., CPA
President Cape Fear Valley Health Foundation Board of Trustees
Member Cape Fear Valley Health System Board of Trustees

North Carolina General Assembly
House of Representatives
Legislative Building
Raleigh 27601-1096

Former / Retired

REPRESENTATIVE JOHN W. "BILL" HURLEY
18TH DISTRICT
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July 31, 2007

DFS Health Planning
RECEIVED
AUG 02 2007
Medical Facilities Planning Section

Mr. Tom Elkins
Medical Facilities Planning Section
The Division of Health Service Regulation
2714 Mail Service Center
Raleigh, NC 27699-2714

Dear Mr. Elkins:

Recently, I received information from Cape Fear Valley Medical Health System (CFVHS) advising that a request for a CyberKnife Stereotactic Radiosurgery System was denied by your section.

I would like to request that due to the significance of the geographic location and the population in our region you reverse this decision, make an adjustment to need determination, and grant this certification of need for the CyberKnife Stereotactic Radiosurgery System. Our military base alone will increase by 2,100 people before the year 2010. As you know, our area is still the predominate metro-hub in southeastern North Carolina, and I feel the requested system would be of great value to the citizens of Cumberland and surrounding counties.

Your consideration of this request is appreciated, and if you have any questions or I can be of further service, please contact me.

Sincerely,

John W. "Bill" Hurley

JWHm

ROBIN HAYES
8TH DISTRICT, NORTH CAROLINA

130 CANNON HOUSE OFFICE BUILDING
WASHINGTON, DC 20515
202-225-3715
FAX: (202) 225-4036
www.house.gov/hayes

COMMITTEES
COMMITTEE ON ARMED SERVICES
COMMITTEE ON AGRICULTURE
COMMITTEE ON TRANSPORTATION AND INFRASTRUCTURE

DISTRICT OFFICES
147 UNION STREET SOUTH
CONCORD, NC 28025
704-786-1612
FAX: 704-782-1004

230 EAST FRANKLIN STREET
ROCKINGHAM, NC 28379
910-997-2070
FAX: 910-997-2987

TOLL FREE IN NC
888-[illegible]

Congress of the United States
House of Representatives

Washington, DC 20515–3308
August 2, 2007

DFS Health Planning
RECEIVED
AUG 09 2007
Medical Facilities
Planning Section

Mr. Tom Elkins
Medical Facilities Planning Section
The Division of Health Service Regulation
2714 Mail Service Center
Raleigh, NC 27699-2714

Dear Mr. Elkins:

I am writing to you on behalf of Cape Fear Valley Health System in Fayetteville, North Carolina. CFVHS has brought to my attention their concern over a need adjustment to the State Medical Facilities plan (SMFP) to add a Cyperknife Stereotactic Radiosurgery System in Area 18, as well as, their intent to file a petition for a need adjustment to The Division of Health Service Regulation in July 2007.

CFVHS has expressed to me their belief that replacing one of its fully-utilized linear accelerators will not best serve patients and that area residents should have access to leading edge technologies accessible to other North Carolina residents.

I thank you for your attention to this issue, and I ask that you give their request your full consideration.

Sincerely,

Robin Hayes

Robin Hayes

HAROLD L. GODWIN, M.D.
1813 Lakeshore Drive
Fayetteville, NC 28305-5240
Phone: (910) 484-8311
Fax: (910) 609-6714
E-mail: hlninagodwin@webtv.net

August 8, 2007

Tom Elkins
Medical Facilities Planning Section
The Division of Health Service Regulation
2714 Mail Service Center
Raleigh, NC 27699-2714

Dear Mr. Elkins:

Please know that I am in support of Cape Fear Valley Health System's request in petitioning for a need adjustment to the State Medical Facilities Plan (SMFP) to add the need for a CyberKnife Stereotactic Radiosurgery System in Area 18. The health system is convinced that replacing one of its fully-utilized linear accelerators will not best serve patients and that area residents should have access to leading edge technologies accessible to other North Carolina residents. As a long time resident of Cumberland County, former practicing Internal Medicine physician, former CEO of the Duke Southern Area Health Education Center, and a strong supporter of healthcare in my community, I know that we need the best possible healthcare and health technology available for the citizens of Cumberland County and this region.

For Cape Fear Valley along with the residents of Area 18 to possibly not be able to gain access to CyberKnife technology considering a) the current linear accelerator methodology, b) the CON section's interpretation that the SMFP demonstrate a need for an accelerator before CyberKnife equipment is acquired, and c) the current utilization rate of Area 18's linear accelerators, in my opinion is unreasonable. Moreover, when need is identified in future SMFPs, Cape Fear Valley or other Area 18 providers may be compelled to add an EBRT linear accelerator given the capacity constraints (surely to be created if one of the current accelerators is replaced). I am convinced that Area 18 is truly in a unique position relative to its large population and its inability to replace a highly utilized linear accelerator with CyberKnife equipment for stereotactic radiosurgery. It doesn't seem fair that areas with fewer capacity constraints should have better access to SRS/SRT services than other areas in North Carolina.

Hopefully, you will be convinced by the reasonable rationale submitted by Cape Fear Valley Health System that a need adjustment to the State Medical Facilities Plan (SMFP) to add the need for a CyberKnife Stereotactic Radiosurgery System in Area 18 is warranted and has merit. Thank you for your sincere consideration of Cape Fear Valley's request.

Sincerely,

Harold L. Godwin, M.D.

BURKHEAD DEVANE inc.
Label Specialists
www.burkheaddevane.com
407 Cumberland Street
Fayetteville, NC 28301
Phone: 800.633.2450
Fax: 910.483.4754
ISO9001:2000

July 31, 2007

Tom Elkins
Medical Facilities Planning Section
The Division of Health Service Regulation
2714 Mail Service Center
Raleigh, NC 27699-2714

Dear Mr. Elkins:

I am writing this letter in support of Cape Fear Valley Health Systems being allowed to have a cyber knife.

I don't know anything about a cyber knife but I do know about the suffering of cancer. I have had prostate cancer for 15 years. Twice I had to take radiation and to date I am taking chemo therapy for bone cancer. In January of this year we discovered that my wife had cancer and had to have her uterus removed in February. In March we found that she had breast cancer, had surgery and then had to have radiation. Because of all of this I have seen cancer patients for 15 years and I know how severe their suffering is and I know that the people of Cape Fear Valley Cancer Center are not only professional, but are the most caring and kind people that you could find anywhere.

I realize that in your job money is more important to you than suffering; however, if you get cancer you'll find out that money becomes very unimportant – you want the people taking care of you to have the best and latest equipment.

The Fayetteville area services over a half million population. Mr. Elkins, Cape Fear Valley Hospital Systems and we cancer patients need and deserve the equipment for the cyber knife.

Sincerely,

James D. DeVane, III

cc: J.Korzen, L. Clark

Health & Healing
2623 Westchester Drive
Fayetteville, NC 28303-5227

July 31, 2007

Mr. Tom Elkins
Medical Facilities Planning Section
Division of Health Service Regulation
2714 Mail Service Center
Raleigh, NC 27699-2714

Dear Mr. Elkins:

I am writing on behalf of Cape Fear Valley Health System (CFVHS) to request your support in adjusting the definition of "need" for the system. As a retired MCH nursing consultant with the Division of Health Services, I support the need for your agency to oversee allocations of "high- dollar" medical equipment in our State. In my former life, I found that the Cumberland-Bladen-Robeson-Sampson geographic area was always trying to play catch-up with the rest of North Carolina in obtaining the equipment needed to provide appropriate services to the population in three of the geographically largest counties of our State. Because we are still trying to catch up on equipment and because of the geographic size of the area, we needed the Linear Acceleator placed at the Health Pavilion North campus of CFVHS to meet the needs of our citizens.

Today, we are also in a new era for Cape Fear Valley Health System. In addition to the more routine services found in a large medical center, we are ready to provide cutting-edge technology. We are also attempting to reach out to the surrounding counties to meet the needs of the medically underserved population in this large region as well as that of Cumberland County. In addition, Ft. Bragg is one of the bases that is in the process of enlarging under the Base Realignment and Closure (BRAC) recommendations; and, Ft. Bragg is a base of choice for soldiers who have exceptional family member needs. Our neurosurgeons serve both soldiers and their dependents. It is anticipated that we may also see the need for CyberKnife Stereotactic Radiosurgery in this younger population.

Last November we requested approval for the CyberKnife. Please see my attached letter of support dated 11/09/06. Nothing has changed, except my friend, the cancer patient who could have used this type of surgery, has died. We still have the support of the multiple physician practices and people in need. While we still need and utilize the Linear Acceleator when it is appropriate, we also have a need and responsibility to provide cutting-edge technology to the population of Southeastern North Carolina which the CyberKnife Stereotactic Radiosurgery system will provide. While this is a large geographic area, Fayetteville is easily accessible to all major areas in the surrounding

counties. We hope you will consider the placement of the CyberKnife at Cape Fear Valley Health System to meet your objectives: to promote and encourage cost-effective quality health care services and to expand the health care services to an area that is medically underserved. With your support, we, the trustees of Cape Fear Valley Health System, are willing to take on this responsibility.

Thank you in advance for expanding your consideration to enable us to meet the needs of the population of southeastern North Carolina.

Sincerely,

Mary Buie

Mary Buie, RN, MPH, Secretary/Treasurer
Cape Fear Valley Health System Board of Trustees

Cc: Lynda Clark
Joyce Korzen

Health & Healing
2623 Westchester Drive
Fayetteville, NC 28303-5227

November 9, 2006

Ms. Lynda B. Clark
Vice President, Professional Services
Cape Fear Valley Health System
1638 Owen Drive
Fayetteville, NC 28302-2000

RE: Support of CON request for CyberKnife Stereotactic Radiosurgery System

Dear Lynda,

I am writing this letter to support Cape Fear Valley Health System's certificate of need application to expand its ability to provide state-of-the-art-services to the citizens of Cumberland County and southeastern North Carolina.

I was truly excited when I heard the presentation you made at a board of trustees committee meeting. Your presentation was great, but the enthusiasm of Dr. Hugh Bryan, the radiation oncologist was invigorating. I have also talked with Drs. Carol Wadon and Bruce Jaufmann, two great neurosurgeons on staff at Cape Fear Valley and they, too, are excited about the ability they will have to perform finite surgery.

I personally know several people who have had cancer for several years. One is now dealing with metastasis to the lung in a location too close to the spinal column for surgery using our present technical capability. The CyberKnife System would be God-sent for her. I look forward to being able to help people, like my friend, with this new capability. This has been presented to the Cape Fear Valley Health System Board of Trustees,who looks closely at the cost of new technology in relation to the need of our citizens. We overwhelmingly recommended that the CON to pursued.

Cape Fear Valley Health System has the backing of the Board of Trustees, the excitement and commitment of multiple physician specialties and a population in need of this service.

I wish to thank the CON Section for consideration of this request and I strongly encourage the CON Section to approve the Cyberknife Stereotactic Radiosurgery System for Cape Fear Valley.

Sincerely,

Mary G. Buie, RN, MPH, Trustee
Cape Fear Valley Health System

player, inc.
SINCE 1938

P.O. DRAWER 27 / FAYETTEVILLE, NC 28302 / 910.868.2121 / FAX 910.868.2126 / E-MAIL player@playerinc.net

August 1, 2007

Mr. Tom Elkins, Medical Planning Section
The Division of Health Service Regulation
2714 Mail Service Center
Raleigh, NC 27699-2714

Re: Petition for a need adjustment to the SMFP to add CyberKnife
Cape Fear Valley Health System

Dear Mr. Elkins:

It is my understanding that Cape Fear Valley Health System is requesting a need adjustment to the State Medical Facilities Plan (SMFP) to add the need for a CyberKnife Stereotactic Radiosurgery System in Area 18. I certainly support this request.

Cumberland County, along with surrounding counties, is experiencing rapid growth. This is creating major needs important to the number of patients in this large area. This CyberKnife Stereotactic Radiosurgery System is needed to support the treatment needs of the patients and the physicians.

I encourage the Certificate of Need Section to adjust the need determination for development of a CyberKnife Stereotactic Radiosurgery System for our Health System and the citizens of Cumberland County and surrounding area.

Sincerely,

Richard L. Player III
2220 Bayview Drive
Fayetteville, NC 28305

Top of Document

Technology and Equipment Committee Meeting

August 29, 2007

Radiation Oncology Services - Linear Accelerators

Material Related To

Linac Petition-3: Rex Hospital

COMMENTS AND PETITION FOR CORRECTION TO THE INVENTORY

Petitioner:
Rex Hospital
4420 Lake Boone Trail
Raleigh, NC 27607

Represented by:
Rebekah Swain
Director, Strategic Planning
(919) 784-4483

Executive Summary:
Rex Hospital requests that the State Health Coordinating Council adjust the inventory of linear accelerators shown on pages 109 and 111 of the draft 2008 State Medical Facilities Plan to correct the omission of the Franklin Regional Cancer Treatment Center.

Background:
The petitioner, Rex Hospital, is located in Wake County and provides cancer treatment services in the Rex Cancer Center. The Rex Cancer Center was the first accredited comprehensive community cancer center in North Carolina, as designated by the American College of Surgeons. Rex provides radiation therapy services on four linear accelerators, all currently located on its main campus in western Raleigh.

Franklin Regional Cancer Treatment Center is located in Louisburg, Franklin County, NC. Franklin County, together with Wake and Harnett Counties, comprise linear accelerator Service Area 20 as shown in Table 9I, pages 112-114 of the draft 2008 State Medical Facilities Plan ("draft Plan").

Franklin Regional Cancer Treatment Center (FRCTC) began providing services on May 1, 2006, as shown in Exhibit A, an article from the Franklin Times dated July 7, 2006. The article states that the facility was to hold an open house on the following Tuesday, July 11, 2006.

In August 2006, CON Agency Analyst Michael McKillip wrote to FRCTC, requesting documentation of the purchase of the linear accelerator being used to provide radiation therapy services. In September 2006, Lee Whitman, acting as representative for FRCTC, responded to Mr. McKillip's inquiry by providing documentation that the linear accelerator and simulator were purchased below the $250,000 limit in July 2005, before the law changed in August 2005. The CON section has issued no response to this matter. FRCTC continues to treat patients each day on its linear accelerator.

Requested Change:
Rex Hospital respectfully requests that Franklin Regional Cancer Treatment Center be included in the inventory of radiation oncology service providers for Service Area 20. If this change is not made, the inventory will continue to be incorrect and misleading.

Thank you for the opportunity to review the draft Plan and provide our comments.

Exhibit 1

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Presented by The Franklin Times

Search The Franklin Times

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My recent searches

You searched for "cancer treatment center"

results 1 through 25 of 916 sorted by releva
page 1 of 37 :: 1 | 2 | 3 | 4 | 5

Cancer Treatment Center improves quality of care (relevance: 100%, date: July 7, 2006)
Since May 1, the Franklin Regional Cancer Treatment Center has been providing state-of the-art care for patients in and around the county.
The center, located on Jolly Street in Louisburg, brings together chemotherapy and radiation treatment in one location.
?It?s a valuable new resource for local citizens,? said Paige McLaurin, the company?s property and office manager. ?Not only does it make it more convenient for the patients, but it also improves the quality of care by enhancing coordinating the efforts.?

2007 Relay for Life plans get going this Friday night (relevance: 57.4%, date Nov 14, 2006)
As the co-chair of the Franklin County Relay For Life, I would like to take this opportunit to express appreciation to the citizens of Franklin County for supporting the fight against cancer.

Relay for Life: fighting against cancer all year long (relevance: 54.6%, date: Apr 27, 2007)
As I reflect back on Friday night?s Relay For Life (April 20) and the people whose exister has been impacted through despair, loss, hope and victory, it brought back a sad, yet swe remembrance of my Uncle Jim, while suffering from the latter stages of lung cancer still making his way to a nearby Lizard?s Thicket restaurant and allowing me the chance to spend a couple of nights at his home on the outskirts of Columbia S.C., before I headed o to Florida;

RELAY FOR LIFE (relevance: 52.3%, date: Jan 12, 2007)
Variety show
?Famous? New Hope hot dogs, along with homemade french fries, will be sold at New H Christian Church on Saturday, Jan. 13, from 5 to 6 p.m., followed by a variety show at 6:3 p.m.
Proceeds will be donated to the American Cancer Society. Yard Sale
Rock Spring Baptist Church Relay For Life team will have a yard sale Saturday, Jan. 27 (7 a.m. - until), between Jeffrey?s and Annie Lee?s on Highway 39 South. All proceeds will benefit the American Cancer Society. Steak Dinner
Rock Spring Baptist Church Relay For Life team will be hosting a steak dinner Saturday,

Exhibit 1

Cancer Treatment Center improves quality of care

By CAREY JOHNSON, Times Staff Writer

GETTING READY. Assistants Wilma Hooker, left, and Jamie Jenkins, help a patient get ready for a radiation treatment
(Times photo by Carey Johnson)

Since May 1, the Franklin Regional Cancer Treatment Center has been providing state-of-the-art care for patients in and around the county.

The center, located on Jolly Street in Louisburg, brings together chemotherapy and radiation treatment in one location.

?It?s a valuable new resource for local citizens,? said Paige McLaurin, the company?s property and office manager. ?Not only does it make it more convenient for the patients, but it also improves the quality of care by enhancing coordinating the efforts.?

Her husband, Dr. Bob McLaurin Jr., agreed.

Two years ago, a Rocky Mount group of oncologists opened a satellite clinic in Franklin County but could only provide chemotherapy.

Cancer sufferers had to go elsewhere for radiation treatment.

?When they brought chemotherapy treatment here, that was a big step ... but a big element is radiation oncology,? Dr. McLaurin said. ?The two can work together.

?Until recently, (patients) had to go to Henderson, Raleigh or Rocky Mount to receive the radiation treatment.?

That?s because the key mechanism for radiation treatment ? a linear accelerator ? isn?t exactly cheap.

The device, which costs millions of dollars, delivers a uniform dose of high-energy X-ray to the region of the patient?s tumor.

The X-rays can destroy the cancer cells while sparing the surrounding normal tissue.

In the office, oncologists and other staff coordinate a course of care, using patient history, expertise, computer equipment and other devices to treat cancer.

Dr. McLaurin works in the office with Drs. Franciso Castillos and Daniel Crocker.

McLaurin, who?s lived in Wake County for 18 years, though, has been involved in designing and developing new cancer centers for over 20 years, including centers in Missouri and Pennsylvania.

His last four centers have been in North Carolina.

He said Franklin County was a destination spot for him.

?It has always been my goal to be able to develop a center in a small community where we can provide customized care for patients,? he said. ?This is the sixth center and hopefully will be the last.

?I?ve been working to try to get to this point to get into a small community and really participate with its members to try to develop center that would be valuable to all.

?It?s already been quite clear from hospital administrators to the citizens of the community to the Chamber of Commerce that everyone is very supportive of our being here and providing this service to the patients.?

The Franklin County Chamber of Commerce is hosting a ribbon cutting ceremony, set for noon on Tuesday at the center at 113 Jolly St.

Top of Document

Technology and Equipment Committee Meeting

August 29, 2007

Positron Emission Tomography (PET) Scanner Material

Top of Document

Technology and Equipment Committee Meeting

August 29, 2007

Positron Emission Tomography (PET) Scanner Material

Material Related To

PET Petition: The Presbyterian Hospital

PETITION TO THE NORTH CAROLINA STATE HEALTH COORDINATING COUNCIL REGARDING THE NEED DETERMINATION FOR POSITRON EMISSION TOMOGRAPHY SCANNERS IN THE 2008 STATE MEDICAL FACILITIES PLAN

The Presbyterian Hospital ("Presbyterian") herby petitions the North Carolina State Health Coordinating Council ("SHCC"), to adjust the need determination contained in the Proposed 2008 State Medical Facilities Plan ("SMFP") at Table 9M, page 122, to show a need determination for a fixed dedicated positron emission tomography ("PET") scanner in Health Service Area ("HSA") III.

Identification of Petitioner

Presbyterian is a non-profit corporation operating a full service hospital in Charlotte with 463 licensed acute care beds. Presbyterian offers a comprehensive cancer program with two linear accelerators[1] currently in operation. Presbyterian is planning to deploy a third linear accelerator in 2008 in a satellite location in southern Mecklenburg County at Ballantyne.[2] As shown in the Proposed 2008 SMFP, Presbyterian provided 16,659 radiation oncology procedures in the most recent annual period for which information is available. See Exhibit A. As measured by the total ESTV-weighted radiation therapy procedures for FFY 2006 reported in the 2007 Presbyterian Hospital Licensure Renewal application and in the proposed 2008 SMFP, Presbyterian Hospital is the tenth busiest cancer treatment program in the state (64 total facilities) and treats many breast cancer cases. See Exhibit B.

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[1] Two linear accelerators are currently in operation at Presbyterian Hospital. Two additional linear accelerators are refurbished units owned by Presbyterian Hospital, but not in operation at this time. See Exhibit A (2007 TPH LRA, Pages 11-12).

[2] Pursuant to settlement in Project I.D. # F-7518-06.

Presbyterian may be contacted about this Petition directly or through its counsel, at the following addresses:

Presbyterian Healthcare
Fred Hargett, Senior Vice President
Financial Planning & Analysis
200 Hawthorne Lane
Charlotte, NC 28204
Telephone: (704) 384-4000
fmhargett@novanthealth.org

Nelson Mullins Riley & Searborough LLP
Noah H. Huffstetler, III
Counsel for Petitioner
4140 Parklake Avenue, Suite 200
Raleigh, NC 27612
Telephone: (919) 877-3801
noah.huffstetler@nelsonmullins.com

Reason for Proposed Adjustment

On page 121, the Proposed 2008 SMFP provides in pertinent part:

> One additional fixed dedicated PET scanner is needed for each existing fixed PET scanner that was utilized at or above 80% of capacity during the twelve month period reflected in the owner's or operator's 2007 Hospital Licensure Renewal Application on file with the N.C. Division of Facility Services. For the purposes of this determination, the annual capacity of a fixed dedicated PET scanner is (2,600 x .80 = 2,080) procedures....

Applying this methodology, Table 9M on page 122 of the Proposed 2008 SMFP shows no need for an additional fixed PET scanner in HSA III, in which Presbyterian is located. For the period covered by its 2007 annual license renewal application, the twelve months ending September 30, 2006, the utilization rate for Presbyterian's PET scanner was 1,988 procedures, or 76.46% of capacity. This utilization of Presbyterian's equipment, based on PET scans per scanner, ranks third among the twenty-two facilities in North Carolina with fixed PET scanners, but is slightly below the 80% figure[3] which would trigger the need for an additional PET scanner in HSA III using the standard methodology. See Exhibit C.

[3] The 80% figure to trigger need for the next new PET scanner is 2,080 PET scans per year. The Presbyterian Hospital Pet scan volume for FFY 06 is only 92 PET procedures shy of that volume.

However, the data set forth in Exhibit F to this Petition shows that the utilization of Presbyterian's PET scanner continues to grow rapidly, and that its current utilization actually exceeds that necessary to justify an additional PET scanner. As shown Exhibit F, for the 12 months ending November 30, 2006--- just two more months beyond the data reported in the 2008 SMFP for FFY 2006[4]-- Presbyterian's PET scanner was utilized for 2,095 procedures[5], or 81% of its capacity. Thus, by applying the standard methodology utilized in the Proposed 2008 SMFP to information that is more current by only two months, a need for an additional PET scanner within HSA III is easily established. In the alternative, for the 12 months ending December 31, 2006--- one quarter beyond the data reported in the 2008 SMFP for FFY 2006--- Presbyterian's PET scanner was utilized for 2,128 procedures, or 102% of its capacity. See Exhibit F. Thus, again by applying the standard methodology utilized in the Proposed 2008 SMFP to information that is more current by only three months, a need for an additional PET scanner within HSA III is easily established.

It is important to also note that the TPH average PET scans per month in each fiscal year of operation have increased steadily since the Presbyterian Hospital PET scanner began operation in October 2004:

- FFY 2005 TPH Average PET scans per month: 140.4
- FFY 2006 TPH Average PET scans per month: 165.7
- FFY 2007[6] TPH Average PET scans per month: 193.8

[4] FFY 2006 as reported in Table 9K in the proposed 2008 SMFP (page 119) is the period 10/1 05-9/30 06. See Exhibit C.

[5] The Presbyterian Hospital PET scanner volumes for the 12-month period December 1, 2006 through November 2006 are 2,095 PET procedures, which is 15 PET procedures beyond the 2,080 PET scans required to trigger need for a new scanner in HSA III.

[6] Based on annualized FFY 2007 project total volumes of 2,325 PET scans per year (using 8 months of actual data).

The Presbyterian Hospital average PET scans per month for each Fiscal Year (the reporting year for the SMFPs) have increased almost 40% from the time the TPH PET scanner became operational in October 2004 until eight months into FFY 2007[7].

The growth in Presbyterian's PET scanning services is likely not only to continue, but to accelerate. The discussion of PET utilization contained at pages 116-118 of the Proposed 2008 SMFP recognized "the steady growth in the number of clinical studies in which the Centers for Medicare and Medicaid Services ("CMS") authorized reimbursement for PET scanning," and concludes that "the clinical use of PET scanning is increasing rapidly, and the new applications involve the diagnosis of cancer." As shown on Table 9G at pages 108-09 of the Proposed 2008 SMFP, Presbyterian's radiation oncology service ranks tenth among the sixty-four facilities providing that service in North Carolina in the number of procedures performed. Given the robust and growing cancer treatment programs offered by Presbyterian, and the rapidly increasing number of types of cancer for which PET scanning is useful, it is clear that Presbyterian's PET utilization is likely to grow even more quickly in the coming years. See the information on CMS's National Oncologic PET Registry (NOPR) attached as Exhibit G, the June 2007 recommendations of the National Comprehensive Cancer Networks (NCCN) Task Force regarding the use of PET and PET/CT in the evaluation and management of certain types of cancer, attached as Exhibit D, and "Advance for Imaging & Oncology Administrators," noting that recent years, FDG-18-based PET scans have become the main source of biological imaging information for Radiation Therapy, outpacing MRI, CT, and ultrasound, attached as Exhibit H. This is further substantiated

[7] Calculation: (193.8 - 140.4 average scans/mo)/140.4 scans per month = 38% increase from FFY 2004 to FFY 2007 YTD in average number of monthly PET scans at Presbyterian Hospital.

by the letter of Dr. Robert Quarles, Mecklenburg Radiology Associates, Medical Director for Nuclear Medicine and PET, Radiology Department, Presbyterian Hospital, which is attached as Exhibit E to this Petition.

For all of the foregoing reasons, an additional PET scanner should be determined to be needed in HSA III in the 2008 SMFP, and Presbyterian and any other qualified applicant should be permitted to apply for a certificate of need to acquire that additional PET scanner.

Presbyterian also concurs with the Forsyth Medical Center PET Comments presented at the July 20th, 2007 public hearing for the proposed 2008 SMFP that any proposal to change the statewide methodology for making PET scanner need determinations[8] should only be considered in accordance with the established State Health Planning process for inclusion in the 2009 SMFP.

File: PETPetitionPresby08SMFToSHCC07.25.07.FINAL.doc

[8] At the May 2007 meeting of the SHCC's Medical Equipment and Technology Committee, it was suggested that the annual volume threshold to trigger need for the next new fixed PET CT scanner should be increased from the current 2,080 to 2,500 annual PET procedures as early as the 2008 SMFP. Further discussion of this issue has been put on the Agenda for a DFS Health Facilities Planning Section-sponsored Discussion Group meeting set for August 15, 2007, a date that is after the close of the public hearing comment period on the 2008 proposed SMFP.

EXHIBIT A

12. Radiation Oncology Treatment Data *continued*

a.	Number of unduplicated patients who receive a course of radiation oncology treatments (patients shall be counted more than once if they receive additional courses of treatment)	541
b.	Total number of Linear Accelerator(s) *	4
c.	Number of Linear Accelerators configured for stereotactic radiosurgery	Ø

* One linacs was the subject of a replacement equipment CON application in March, 2006.

12. Telemedicine

a. Does your facility utilize telemedicine to have images read at another facility? no

b. Does your facility read telemedicine images? yes

13. Additional Services:

a) **Check if Service(s) is provided:**

	Check		Check
1. Cardiac Rehab Program (Outpatient)	✓	5. Rehabilitation Outpatient Unit	
2. Chemotherapy	✓	6. Podiatric Services	
3. Clinical Psychology Services	✓	7. Genetic Counseling Service	✓
4. Dental Services		8. Acute Dialysis	✓

Number of Acute Dialysis Stations 10

b) **Hospice Inpatient Unit Data:**
Hospital-based hospice units with licensed hospice beds. List each county served and report **all patients by county of residence.** Use each patient's age on the admission day to the Licensed Hospice Inpatient Facility. **For age categories count each inpatient client only once.**

County of Residence	Age 0-17	Age 18-40	Age 41-59	Age 60-64	Age 65-74	Age 75-84	Age 85+	Total Patients Served	Total Days of Care	Deaths
		See supplemental sheet on the next page								
		for detail of the total								
Out of State										
Total All Ages	Ø	10	74	28	84	156	113	465	2,215	326

* In June 2005 TPH purchased and now owns 2 additional linear accelerators; these linear accelerators are not operational at this time.

EXHIBIT A

11. Radiation Oncology Treatment Data

CPT Code	Description	Number of Procedures	ESTVs/ Procedures Under ACR	Total ACR ESTVs	
	Simple Treatment Delivery:				
77401	Radiation treatment delivery	140	1.00	140	
77402	Radiation treatment delivery (<=5 MeV)	Ø	1.00		
77403	Radiation treatment delivery (6-10 MeV)	161	1.00	161	
77404	Radiation treatment delivery (11-19 MeV)	84	1.00	84	
77406	Radiation treatment delivery (>=20 MeV)	Ø	1.00		
	Intermediate Treatment Delivery:				
77407	Radiation treatment delivery (<=5 MeV)	Ø	1.00		
77408	Radiation treatment delivery (6-10 MeV)	15	1.00	15	
77409	Radiation treatment delivery (11-19 MeV)	2	1.00	2	
77411	Radiation treatment delivery (>=20 MeV)	Ø	1.00		
	Complex Treatment Delivery:				
77412	Radiation treatment delivery (<=5 MeV)	Ø	1.00		
77413	Radiation treatment delivery (6-10 MeV)	4,270	1.00	4270	
77414	Radiation treatment delivery (11-19 MeV)	5029	1.00	5029	
77416	Radiation treatment delivery (>= 20 MeV)	35	1.00	35	
	Sub-Total	9736		9736	

For the increased time required for special techniques, ESTV values are indicated below:

77417	Additional field check radiographs	6425	.50	3,213	
77418	Intensity modulated radiation treatment (IMRT)delivery	3685	1.00	3685	
77432	Stereotactic radiosurg. treatment mgmt Linear Accelerator	Ø	3.00		
77432	Stereotactic radiosurg. Treatment mgmt. Gamma Knife	Ø	3.00		
	Total body irradiation	Ø	2.50		
	Hemibody irradiation	Ø	2.00		
	Intraoperative radiation therapy (conducted by bringing the anesthetized patient down to the linac)	Ø	10.00		
	Neutron and proton radiation therapy	Ø	2.00		
	Limb salvage irradiation	Ø	1.00		
	Pediatric Patient under anesthesia	3	1.50	4.5	
	Sub-Total	10113		6902.5	
	TOTALS:	19,849		16,658.5	

Note: For special techniques, list procedures under both the treatment delivery and the special techniques sections.

EXHIBIT B

EXHIBIT B

Table 9G: Hospital and Free-Standing Linear Accelerators and Radiation Oncology Procedures (see note at bottom of table)

Facility Name	Service Area #	County	LIN ACC	PROCEDURES (ESTVs) 2005-2006	Average per Unit
Harris Regional Hospital, Inc.-Mtn Trace	1	Jackson	1	4,503	4,503
NC Radiation Therapy - Franklin	1	Macon	1	2,277	2,277
Mission Hospitals (S) (b)	2	Buncombe	3	20,766	6,922
NC Radiation Therapy - Asheville	2	Buncombe	2	7,012	3,506
NC Radiation Therapy - Clyde	2	Haywood	1	4,359	4,359
NC Radiation Therapy - Marion	2	McDowell	1	2,534	2,534
Watauga Hospital	3	Watauga	1	4,491	4,491
Margaret Pardee Mem. Hospital	4	Henderson	1	6,591	6,591
NC Radiation Therapy - Brevard	4	Transylvania	1	1,709	1,709
NC Rad.Therapy - Hendersonville	4	Henderson	1	645	645
Catawba Valley Medical Center	5	Catawba	2	18,008	9,004
Frye Regional Medical Center	5	Catawba	1	NA	NA
Grace Hospital, Inc.	5	Burke	1	NR	NR
Valdese General	5	Burke	1	6,082	6,082
Caldwell Memorial Hospital, Inc.	5	Caldwell	1	1,056	1,056
Cleveland Regional	6	Cleveland	1	6,989	6,989
Gaston Memorial Hospital (h)	6	Gaston	3	11,761	3,920
NC Radiation Therapy - Forest City	6	Rutherford	1	4,656	4,656
2006 SMFP Need Determination	7		1		
Carolinas Medical Center (S)	7	Mecklenburg	3	14,128	4,709
CMC-Union Reg. Medical Center (i)	7	Union	1	8,428	8,428
Matthews Radiation Oncology	7	Mecklenburg	1	10,803	10,803
Presbyterian Hospital	7	Mecklenburg	4	16,659	4,165
University Radiation Oncology	7	Mecklenburg	1	7,289	7,289
Iredell Memorial	8	Iredell	2	6,834	3,417
Lake Norman Radiation Oncology Ct	8	Iredell	1	4,641	5,525
Rowan Regional Medical Center	8	Rowan	1	5,519	5,519
NorthEast Medical Center	9	Cabarrus	2	13,009	6,505
Stanly Regional Medical Center	9	Stanly	1	4,427	4,427
Forsyth Memorial Hospital	10	Forsyth	4	28,435	7,109
Hugh Chatham Memorial Hospital (d)	10	Surry	1	3,911	3,911
N. C. Baptist Hospitals (S)	10	Forsyth	4	20,251	5,063
2006 SMFP Need Determination	11	Davidson	1		
High Point Regional Health System	12	Guilford	2	9,344	4,672
Morehead Memorial Hospital	12	Rockingham	1	5,972	5,972
Moses Cone Health System	12	Guilford	4	28,362	7,091
Randolph Cancer Center (m)	13	Randolph	1	NA	NA
UNC Hospitals (S)	14	Orange	4	22,224	5,556

EXHIBIT B

Table 9G: Hospital and Free-Standing Linear Accelerators and Radiation Oncology Procedures (see note at bottom of table)

Facility Name	Service Area #	County	LIN ACC	PROCEDURES (ESTVs) 2005-2006	PROCEDURES (ESTVs) Average per Unit
Alamance Regional Medical Center (j)	15	Alamance	2	7,991	3,996
Duke University Hospital (S)	16	Durham	5	36,634	7,327
Durham Regional Hospital	16	Durham	1	6,128	6,128
Maria Parham Hospital (e)	16	Vance	1	4,833	4,833
FirstHealth Moore Regional	17	Moore	2	23,764	11,882
Scotland Memorial Hospital (1)	17	Scotland	1	4,122	4,122
Cape Fear Valley Medical Center (a)	18	Cumberland	4	27,631	6,908
Southeastern Regional Medical Center	18	Robeson	1	9,484	9,484
New Hanover Radiation Oncology	19	New Hanover	2	15,156	7,578
New Hanover Regional Med Ctr	19	New Hanover	1	7,599	7,599
South Atlantic Radiation Oncology, LLC (c)	19	Brunswick	1	NA	0
2007 SMFP Need Determination	20		1		
Cancer Ctrs of NC - Raleigh Hematology	20	Wake	1	8,924	8,924
Duke Raleigh Hospital	20	Wake	1	7,323	7,323
Rex Hospital	20	Wake	4	16,184	4,046
Wake Radiology Oncology Services	20	Wake	1	5,960	5,960
Triangle Radiation Oncology Services	21	Johnston	1	2,648	1,093
2006 SMFP Need Determination	21	Johnston	1		
Lenoir Memorial	22	Lenoir	1	6,147	6,147
Wayne Radiation Oncology Center	22	Wayne	1	6,952	6,952
Carteret General (g)	23	Carteret	1	4,015	4,015
Craven Regional Med Ctr	23	Craven	2	12,415	6,208
2006 SMFP Need Determination	24	Onslow	1		
Nash Day Hospital	25	Nash	2	7,905	3,953
Roanoke Valley Cancer Center	25	Halifax	1	3,208	3,208
Wilson Memorial Hospital	25	Wilson	1	4,413	4,413
Ahoskie Cancer Center	26	Hertford	1	3,173	3,173
Carolina Radiation Medicine, P.A. (f) (S)	26	Pitt	1	8,206	8,206
Pitt County Memorial Hospital (S)	26	Pitt	3	16,013	5,338
Albemarle Hospital	27	Pasquotank	1	4,403	4,403
Outer Banks Cancer Center	27	Dare	1	4,977	4,977
TOTALS (64 Facilities)			**112**	**579,883**	**5,178**

1
5
4

Note: The above inventory of linear accelerators is subject to change if it is determined that any of the listed equipment was not acquired in accordance with N.C. G. S. 131E-175, et.seq. prior to August 26, 2005.

T9G2008p.xls (06/6/2007)

Exhibit C

Proposed 2008 SMFP

Table 9K: PET Scanner Utilization of Existing Fixed Dedicated Scanners

Center	Procedures 2002-2003	Procedures 2003-2004	Procedures 2004-2005	Procedures 2005-2006	HSA	Inventory	Utilization Rate Year 2006 Procedures / 2600 as Capacity	Need Determination by Criteria - 80% of Present Capacity
Mission Hospitals (f)		644	875	1003	I	1	38.58%	
Catawba Valley/ Frye Reg. (j)			848	1258	I	1	48.38%	
N.C. Baptist Hospitals	1817	1797	1266	1477	II	1	56.81%	
Moses Cone Health System (o)			1352	1760	II	1	67.69%	
Forsyth Medical Center (p)		130	1579	2417	II	1	92.96%	1
High Point Regional (r)		179	356	574	II	1	22.08%	
Alamance Reg. Medical Ctr. (u)				374	II	1	14.38%	mobile procedures
Carolinas Med Center(a),(k)	2414	2908	3049	3635	III	2	69.90%	1818/Scanner
Gaston Mem. / CTS Summit (m)		172	700	846	III	1	32.54%	
NorthEast Medical Center (n)		330	481	615	III	1	23.65%	
The Presbyterian Hospital (q)			1544	1988	III	1	76.46%	
Iredell Memorial Hospital (t)				NA	III	1	NA	
Duke Univ. Hospital (d)	3259	3135	3091	3596	IV	2	69.15%	1798/Scanner
UNC Hospitals (b)	1230	1389	1144	1386	IV	2	26.65%	693/Scanner
Rex Hospital (e)	407	1116	1544	1913	IV	1	73.58%	
Wake PET Services, Wake Radiology Oncology, Wake Radiology, WakeMed (s)				NA	IV	1		
New Hanover Reg. Med. (g)			582	755	V	1	29.04%	
Cape Fear Valley Medical Ctr. (h)		629	1218	2069	V	1	79.58%	0
First Imaging of the Carolinas (i)		351	529	550	V	1	21.15%	
Pitt Co. Memorial (c)		418	393	832	VI	1	32.00%	
Craven Reg. Medical (l)			719	831	VI	1	31.96%	
Nash General Hospital (u)				336	VI	1	12.92%	mobile procedures
TOTAL	9,127	13,198	21,270	28,215		25		1

t9k2008p.xls (6/18/2007)

NA Not Applicable for time period ending September 30, 2006.

(a) Approved for additional scanner in November 2001.
(b) Approved for scanner in June 2000 and additional scanner under Policy AC-3 in November 2005.
(c) Approved for scanner in August 2001.
(d) Approved for additional scanner under Policy AC-3 in September 2002.
(e) Approved for scanner in September 2002.
(f) Approved for scanner in January 2003.
(g) Operational in October 2004.
(h) Approved for scanner in August 2003.
(i) Approved for scanner in August 2003.
(j) Approved for scanner in July 2003.
(k) Approved for replacement of 1 scanner in June 2003.
(l) Approved for scanner in October 2003.
(m) Approved for scanner in December 2003.
(n) Approved for scanner in December 2003.
(o) Operational in October 2004.
(p) Approved for scanner in June 2004.
(q) Approved for scanner in June 2004.
(r) Approved for scanner in January 2005.
(s) Approved for scanner in November 2005.
(t) Approved for scanner in January 2007.
(u) Approved for scanner in April 2007.
(v) Approved for scanner in May 2007

Exhibit D

NCCN Task Force Develops Clinical Recommendations for PET in Cancer Evaluation and Management

JENKINTOWN, Pa , June 5, 2007 — The National Comprehensive Cancer Network (NCCN) will publish a special report entitled *NCCN Task Force Report: Positron Emission Tomography (PET)/Computed Tomography (CT) Scanning in Cancer* as a supplement to the May issue of its journal. The report is the work of a Task Force convened by NCCN to develop clinical recommendations for the use of PET and PET/CT in the evaluation and management of certain types of cancer

PET is a non-invasive imaging technique used frequently to detect cancer and assess the effects of cancer treatment. However, PET is more costly than other traditional types of imaging. The report, to be published in the *Journal of the National Comprehensive Cancer Network (JNCCN)*, addresses this challenge and offers recommendations as to when PET is appropriate and most useful.

The Task Force, made up of expert radiologists, surgeons, radiation oncologists and medical oncologists from NCCN Member Institutions, studied existing data to create their recommendations. According to the Task Force Report, "The role of PET or PET/CT scans in oncology is rapidly evolving, with well-defined roles in the common malignancies of breast, lung, colorectal cancer, and lymphoma." In response to concerns about economics, the report suggests that PET can sometimes reduce costs. For example, PET scans can be cost-saving when the results are used to prevent unnecessary surgeries

"The role of PET or PET/CT scans in oncology is rapidly evolving," said Donald Podoloff, MD, chair of the Task Force and head of the Division of Diagnostic Imaging at The University of Texas M. D. Anderson Cancer Center. "With the collective expertise of this Task Force, we were able to make recommendations for appropriate use of this technology. As a result, we hope that PET and PET/CT will demonstrate its cost effectiveness and value to patients, physicians and managed care providers. The rapid acceptance of PET/CT is a testimony to the unique, noninvasive and important information it provides to oncologists as they manage their patients."

The report will be published as a supplement to *JNCCN*, a nationally recognized, peer-reviewed medical journal received by more than 21,000 oncologists and other cancer care professionals across the United States

For questions about NCCN or for interview information, please contact Thomas Mitchell at 215 690 0245.

About the National Comprehensive Cancer Network

The National Comprehensive Cancer Network (NCCN), a not-for-profit alliance of 21 of the world's leading cancer centers, is dedicated to improving the quality and effectiveness of care provided to patients with cancer. Through the leadership and expertise of clinical professionals at NCCN Member Institutions, NCCN develops resources that present valuable information to the numerous stakeholders in the health care delivery system. As the arbiter of high-quality cancer care, NCCN promotes the importance of continuous quality improvement and recognizes the significance of creating clinical practice guidelines appropriate for use by patients, clinicians, and other health care decision-makers. The primary goal of all NCCN initiatives is to improve the quality, effectiveness, and efficiency of oncology practice so patients can live better lives

The NCCN Member Institutions are:

- City of Hope
- Dana-Farber/Brigham and Women's Cancer Center

Massachusetts General Hospital Cancer Center
- Duke Comprehensive Cancer Center
- Fox Chase Cancer Center
- Huntsman Cancer Institute at the University of Utah
- Fred Hutchinson Cancer Research Center / Seattle Cancer Care Alliance
- Arthur G. James Cancer Hospital & Richard J. Solove Research Institute at The Ohio State University
- The Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins
- Robert H. Lurie Comprehensive Cancer Center of Northwestern University
- Memorial Sloan-Kettering Cancer Center
- H. Lee Moffitt Cancer Center & Research Institute at the University of South Florida
- Roswell Park Cancer Institute
- Siteman Cancer Center at Barnes-Jewish Hospital and Washington University School of Medicine
- St. Jude Children's Research Hospital / University of Tennessee Cancer Institute
- Stanford Comprehensive Cancer Center
- University of Alabama at Birmingham Comprehensive Cancer Center
- UCSF Comprehensive Cancer Center
- University of Michigan Comprehensive Cancer Center
- UNMC Eppley Cancer Center at The Nebraska Medical Center
- The University of Texas M. D. Anderson Cancer Center
- Vanderbilt-Ingram Cancer Center

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July 25, 2007

Chris Ullrich, M.D., Chair
Medical Equipment and Technology Committee
State Health Coordinating Council
701 Barbour Drive
Raleigh, NC 27603

Subject: Petition to the State Health Coordinating Council Regarding the Need Determination for One New PET Scanner for HSA III in the Proposed 2008 State Medical Facilities Plan

Dear Dr. Ullrich:

I support the amendment of the proposed 2008 State Medical Facilities Plan, for the addition of Need Determination for one new fixed dedicated positron emission tomography (PET) scanner in Health Service Area (HSA) III. An additional scanner is needed as PET services will clearly continue to grow and Presbyterian Hospital's PET scanner's FFY 2006 PET procedures are only 4% shy[1] of the threshold for a new PET scanner set forth in the proposed 2008 SMFP.

The Presbyterian Hospital began offering PET services in October 2004 and since then we have completed almost 5,000 exams[2]. As shown below, the average number of exams per month has increased steadily and is currently almost 195 per month. Currently, well over 95% of these exams have been completed on oncology patients. The Presbyterian Hospital (TPH) Cancer Center is one of the top ten busiest cancer centers in the state of the 64 North Carolina cancer treatment centers, when measured by the number of ESTV radiation therapy treatments offered during FFY 2006 as reported in the proposed 2008 SMFP.[3] TPH will deploy a third linear accelerator in 2008 in a satellite location in southern Mecklenburg County at Ballantyne. TPH's Cancer program provides care to a large number of breast cancer cases, which is in large measure related to the subspecialty radiologists, the imaging equipment (including PET and MRI), the cancer center physicians and surgeons and the linear accelerators and other treatment options. Thus, a second PET scanner will become necessary to keep up with the growing demand from cancer physicians and their patients.

With regard to PET growth, the National Oncologic PET Registry (NOPR) was established in 2005 to respond to a proposal by the Centers for Medicare and Medicaid Services (CMS) to expand coverage for PET with F-18 fluorodeoxyglucose (^{18}FDG) to include cancers and indications not presently eligible for Medicare reimbursement. Prior to May 2006 when the NOPR began registering patients to capture data on additional diagnostic indications for the use of PET scans, CMS paid for PET scans for only nine types of cancer. See attached Table from the NOPR website (http://www.cancerpetregistry.org) showing the types of PET scans that are already covered for Medicare reimbursement (designated with a "C") and the types of cancers and indications for which Medicare reimbursement is available thorough the NOPR (designated with a "checkmark") if the patient's referring physician and the provider submit data to the clinical registry to assess the impact of PET diagnostic information on cancer patient management. See Exhibit E attached to The Presbyterian Hospital Petition. Sponsored by the Academy of

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[1] Calculation: (2,080 PET px threshold 08 SMFP - 1,988 TPH PET px FFY 06)/ 2,080) = 4.4%

[2] Calculation of Presbyterian Hospital PET scan volumes from October 2004 through May 2007: (FFY 2005 at 1,544) + (FFY 2006 at 1,988) + (FFY 07 Year to Date/8 months at 1,550 and FFY 2007 annualized at 2,325). Thus total PET and PET/CT exams at Presbyterian Hospital for Oct 2004 – May 2007 = 5,082 (1544 + 1988 + 1550).

[3] Based on E STV-weighted radiation therapy procedures report in the Proposed 2008 SMFP: (1) Duke at 36,634; (2) FMC at 28,435; (3) Moses Cone Health System at 28,362; •4) Cape Fear Valley Medical Center at 27,631; (5) First Health Moore Regional at 23,764; (6) UNC Hospitals at 22, 224; (7) Mission Hospitals at 20,776; (8) NCBH at 20,251; (9) Catawba Valley Medical Center at 20,766; (10) The Presbyterian Hospital at 16,659.

Molecular Imaging and managed by the American College of Radiology (ACR) through the ACR Imaging Network, the NOPR is implementing this registry for CMS. Considering the impact of the NOPR, PET will surely continue to grow as the CMS begins to cover for more cancers, the diagnosis, initial staging, treatment monitoring during therapy (chemotherapy, radiation therapy, or combined modality therapy) and re-staging after completion of therapy and detection of suspected recurrence.

Practically, the hours of operation for a PET/CT scanner at facilities such as PH are more limited than suggested by the state. Unlike CT or MRI that must operate 66 hours per week as per 10A NCAC 14C.2302(k) or 10A NCAC 14C.2702(c)(1), respectively, PET/CT Scanners are being held to an operational standard of 72 hours per week per 10A NCAC 14C.3702(b)(3)(B). Perhaps this requirement is based upon the lengthy total exam time of approximately 2 to 2.5 hours for PET. For example at TPH, the uptake time of the ^{18}FDG is generally 90 to 120 minutes, followed by a scan that takes approximately 30 minutes. But, unlike CT and MRI that are used for innumerable indications, PET is used for a small subset of the general patient population that includes primarily oncology patients, and some cardiac and Alzheimer's patients. Furthermore, unlike CT and MRI which may be staffed to operate 24 hours a day to meet urgent and emergent needs, the daily PET schedule is limited to the availability of the cyclotron-produced ^{18}FDG from regional vendors. At Presbyterian Hospital, we can scan a maximum of 14 patients per day and we have gained all the exam efficiency that is feasible. We must also take into account for certain PET studies the following complicating factors, some of which we can anticipate and some we cannot: late patients, diabetics, very ill patients (and the potential for radioactive body fluids), certain diseases requiring whole body PET scans, occasional sedation, and patients requiring interpreters.

One option to increase the productivity of the single PET/CT scanner at Presbyterian Hospital is to install a cyclotron to increase available hours of production. However, it is not a feasible alternative for Presbyterian Hospital to seek to add a cyclotron on site, as that equipment is regulated by both state CON and the federal United States Pharmacy 797 regulations (USP 797). USP 797 became effective in North Carolina and six other states in January 2007 and imposes a strict regulatory framework on the operation of cyclotron "hot labs" producing radiopharmaceuticals in NC. Thus, it is more cost effective for the large tertiary community hospital cancer and PET centers to purchase the radiopharmaceuticals from established third party vendors. In this type of arrangement, centers like the Presbyterian Hospital are limited to the times of day and days of the week when these vendors can produce and deliver the radiopharmaceuticals that are required. On the other hand, it is reasonable for the Academic Medical Centers (AMCs) to have the cyclotron on site to support the early research studies. Many of these cyclotrons were installed prior to the establishment of third party regional distribution centers.
In addition, the growth in the utilization of PET diagnostic studies for the Presbyterian Hospital Cancer Center oncology patient load has not permitted us to fully implement other more complex and time-intense PET studies. For example, radiation treatment planning simulation studies can take as much as three times the normal scanner time of 30 minutes. Radiation Therapy treatment planning exams are time intensive and would be more available if TPH had more PET scanner capacity. Newer applications for cardiology patients have not been implemented because of the current time constraints. We anticipate that both of these applications may increase our PET volume, when we have adequate scanner time available. Since the availability of TPH's one PET/CT scanner is limited to just 14 patients per day as described above, we look forward to the opportunity to seek the state's approval for a second PET/CT scanner in 2008.

We have projected, conservatively, that the TPH PET annual PET scanner volumes will range from 2,600 to 2,900 by the end of CY 2009. Thus, if we are to plan in a way that allows our PET diagnostics to remain readily available to a growing variety of referring physicians and their patients, we must apply in the 2008 year to seek the state's approval for a second PET/CT scanner, which can be implemented in 2009. Otherwise, we think it is quite likely that the TPH PET scanner will reach the practical limits of its capacity and access to this valuable diagnostic service will be compromised. See Exhibit F.

Presbyterian HOSPITAL

Remarkable People. Remarkable Medicine.

Thank you for the opportunity to present this letter in support of an amendment to proposed 2008 State Medical Facilities Plan to show the a need for one additional PET scanner in Health Service Area (HSA) III, which includes Mecklenburg County. If I may provide additional information, please contact me at (336)-384-4056.

Sincerely,

Robert Quarles, M.D., Medical Director, Nuclear Medicine and PET
Mecklenburg Radiology Associates
and
Department of Radiology
The Presbyterian Hospital

File: PETTPHPetitionO8SMFPQuarlesRadiologistLetter.07.25.07.doc

Presbyterian Hospital - PET Procedures
Inpatient & Outpatient - Combined Discharges Dated 01/01/2004 - 05/31/2007
Department 3927 - PET

EXHIBIT F

Oct 04 Units	Nov 04 Units	Dec 04 Units	Jan 05 Units	Feb 05 Units	Mar 05 Units	Apr 05 Units	May 05 Units	Jun 05 Units	Jul 05 Units	Aug 05 Units	Sep 05 Units	Oct 05 Units	Nov 05 Units	Dec 05 Units
67	100	74	109	114	110	132	163	164	176	178	157	125	166	172
											1544			
											FFY 2005 Oct 04 thru Sep 05			

File: PETProeduresTPHNov04.May07.xls

Avg PET Scans/Month----> ***140.4***

Exhibit F

Jan 06 Units	Feb 06 Units	Mar 06 Units	Apr 06 Units	May 06 Units	Jun 06 Units	Jul 06 Units	Aug 06 Units	Sep 06 Units
160	161	209	165	174	151	140	203	162

1988

FFY 06 Total Oct 05 thru Sep 06

165.7

Avg PET Scans/Month——>

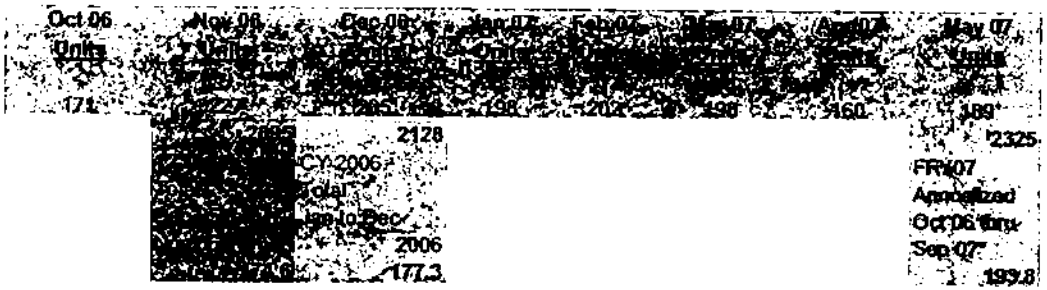


EXHIBIT F

PRESBYTERIAN PET SCANS CALENDAR YEAR (2004 - 2009)

(assumes future PET volume growth of 2% per Quarter)

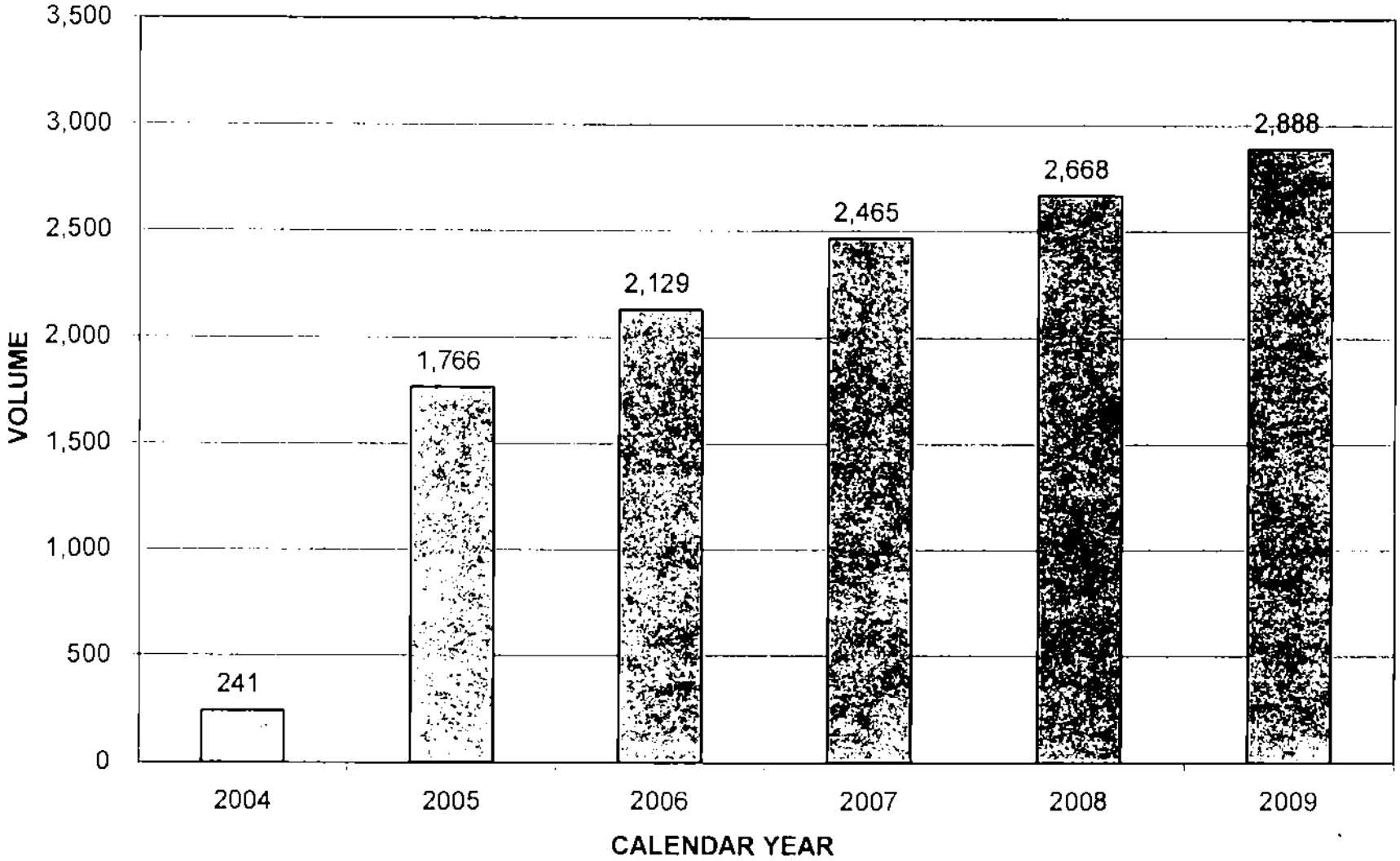


EXHIBIT G

Source: NOPR Website

Cancers and indications that are reimbursable by Medicare are NOT eligible for entry in the NOPR. Cancers and indications that are specifically excluded for Medicare reimbursement are also not eligible for entry in the NOPR.

IMPORTANT NOTE: The scientific evidence concerning the clinical utility of FDG-PET is generally less robust for cancers and indications that are currently covered by Medicare only in the NOPR than for cancers and indications that are currently covered without clinical data submission to the NOPR. For this reason, Medicare has conditioned coverage of FDG-PET under the NOPR on the collection of clinical data. These data will be used to help determine the clinical utility of FDG-PET for conditionally covered cancers and indications. The billing physician remains responsible for documenting medical necessity, which is required for the coding and billing of both covered and NOPR-eligible PET studies. Eligibility for the NOPR does not constitute a clinical management recommendation for the use of PET for the conditionally covered cancers and indications, by either the Medicare program or NOPR investigators. Referring and interpreting physicians are thus advised to refer to the published literature to better understand the potential limitations of FDG-PET for NOPR-eligible uses.

CANCERS AND INDICATIONS ELIGIBLE FOR ENTRY IN THE NOPR

✓ = Eligible for Entry in NOPR

C = Not Eligible for Entry in NOPR - nationally covered indication.

NC = Not Eligible for Entry in NOPR - nationally non-covered indication.

NA = Not Applicable

Indications	Diagnosis	Initial Staging	Treatment Monitoring	Restaging/Suspected Recurrence
Lip, Oral Cavity, and Pharynx (140-149)	C	C	✓	C
Esophagus (150)	C	C	✓	C
Stomach (151)	✓	✓	✓	✓
Small Intestine (152)	✓	✓	✓	✓
Colon (153) and Rectum (154)	C	C	✓	C
Anus (154)	✓	✓	✓	✓
Liver and intrahepatic bile ducts (155)	✓	✓	✓	✓

Gallbladder & extrahepatic bile ducts (156)	✓	✓	✓	✓
Pancreas (157)	✓	✓	✓	✓
Retroperitoneum and peritoneum (158)	✓	✓	✓	✓
Nasal cavity, ear, and sinuses (160)	C	C	✓	C
Larynx (161)	C	C	✓	C
Lung, non-small cell (162)	C	C	✓	C
Lung, small cell (162)	✓	✓	✓	✓
Pleura (163)	✓	✓	✓	✓
Thymus, heart, mediastinum (164)	✓	✓	✓	✓
Bone/cartilage (170)	✓	✓	✓	✓
Connective/other soft tissue (171)	✓	✓	✓	✓
Melanoma of skin (172)	C	C[2]	✓	C
Female breast (174)	NC[3]	C[4]	C	C
Male breast (175)	NC[3]	C[4]	C	C
Kaposi's sarcoma (176)	✓	✓	✓	✓
Uterus, unspecified (179)	✓	✓	✓	✓
Cervix (180)	✓	C[4]	✓	✓
Uterus, body (182)	✓	✓	✓	✓
Ovary and uterine adnexa (183)	✓	✓	✓	✓
Prostate (185)	✓	✓	✓	✓
Testis (186)	✓	✓	✓	✓

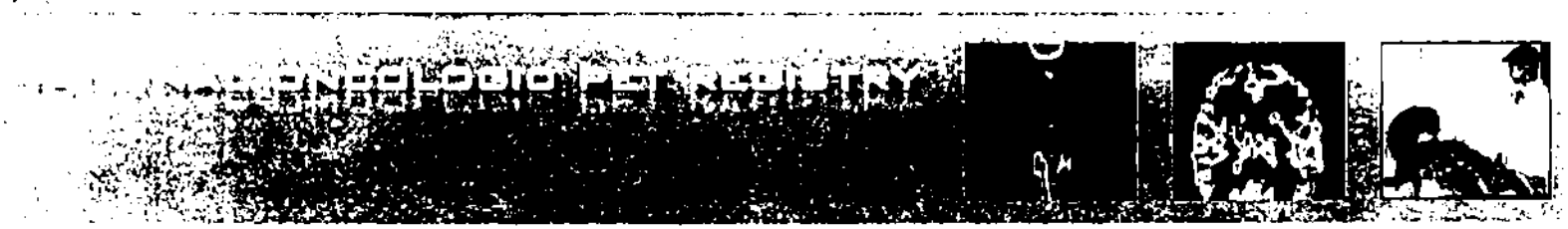
Penis and other male genitalia (187)	✓	✓	✓	✓
Bladder (188)	✓	✓	✓	✓
Kidney and other urinary tract (189)	✓	✓	✓	✓
Eye (190)	✓	✓	✓	✓
Primary Brain (191)	✓	✓	✓	✓
Thyroid (193)	✓	✓	✓	C[5]
Lymphoma (200-202)	C	C	✓	C
Myeloma (203)	✓	✓	✓	✓
Leukemia (204-208)	✓	✓	✓	✓
Solitary Pulmonary Nodule	C	NA	NA	NA
Other or not listed	✓	✓	✓	✓

NOTES:

1. Some Medicare carriers include anal cancer in their coverage of "colorectal cancer"; for PET facilities served by those carriers, PET for anal cancer diagnosis, initial staging, or restaging/suspected recurrence would be a covered indication.
2. Does not cover initial staging for axillary lymph nodes for breast cancer patients and regional lymph nodes for melanoma patients
3. PET is non-covered for "Diagnosis" of breast cancer to evaluate a suspicious breast mass. However, a patient with suspected breast cancer is eligible for entry in NOPR for the indications (1) "Diagnosis: Unknown Primary Site" in a patient with axillary nodal metastasis but no evident primary breast cancer by conventional evaluation and (2) "Diagnosis: Paraneoplastic Syndrome".
4. Patient must have prior CT or MRI negative for extrapelvic metastatic disease to qualify as a covered indication. Patients who do not qualify for covered indication (e.g., because CT or MRI not done or because either showed extrapelvic metastatic disease) can be entered on NOPR.
5. To qualify as a covered indication thyroid cancer must be of follicular cell origin and been previously treated by thyroidectomy and radioiodine ablation and have a serum thyroglobulin > 10ng/ml and negative I-131 whole body scan. Patients who do not qualify for covered indication (e.g., because tumor of other than follicular cell origin or thryoglobulin not elevated) can be entered on NOPR.

GENERAL NOTE:
PET imaging of the brain with CPT code 78608 for diagnosis, initial staging, treatment monitoring, or restaging/suspected recurrence of any type of cancer is covered only under NOPR.

EXHIBIT G



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What is the NOPR

NOPR Background

The National Oncologic PET Registry (NOPR) was developed in response to the Centers for Medicare and Medicaid Services proposal to expand coverage for positron emission tomography with F-18 fluorodeoxyglucose (PET) to include cancers and indications not presently eligible for Medicare reimbursement. Medicare reimbursement for these cancers can now be obtained if the patient's referring physician and the provider submit data to a clinical registry to assess the impact of PET on cancer patient management. The NOPR is implementing this registry for CMS. The NOPR is sponsored by the Academy of Molecular Imaging and managed by the American College of Radiology through the American College of Radiology Imaging Network.

The NOPR received input from, and is endorsed by the ACR, the American Society for Clinical Oncology, and the Society for Nuclear Medicine.

NOPR Status Update

The NOPR began accepting facility registrations in late November 2005 and patient registration began on May 8, 2006.

How to Register as a Participating Site

Any PET facility that is approved to bill CMS for either technical or global charges can apply to participate in the NOPR. Sites are not required to have ACR or ICANL accreditation to participate. Interested facilities will register via the Facility Registration tool on the NOPR Web site, www.CancerPETregistry.org. The facility will complete the Facility Pre-Registration and Registration Forms online through the PET Facility Registration link. After completing the Registration process the facility must send an executed ACR HIPAA Business Associates Agreement (BAA) to NOPR Headquarters at 1818 Market Street, Philadelphia, PA 19103. The ACR HIPAA BAA is available on the NOPR Web site under Sample Forms. NOPR will assign a facility ID number and send an invoice for the facility registration fee ($50) and the escrow account (amount determined by the facility).

How to Register as a Participating Site

Any PET facility that is approved to bill CMS for either technical or global charges can apply to participate in the NOPR. Sites are not required to have ACR or ICANL accreditation to participate. Interested facilities will register via the Facility Registration tool on the NOPR Web site, www.CancerPETregistry.org. The facility will complete the Facility Pre-Registration and Registration Forms online through the PET Facility Registration link. After completing the Registration process the facility must send an executed ACR HIPAA Business Associates Agreement (BAA) to NOPR Headquarters at 1818 Market Street, Philadelphia, PA 19103. The ACR HIPAA BAA is available on the NOPR Web site under Sample Forms. NOPR will assign a facility ID number and send an invoice for the facility registration fee ($50) and the escrow account (amount determined by the facility).

Patient Eligibility

Medicare beneficiaries who are referred for PET for essentially all oncologic indications that are not currently reimbursable under Medicare are eligible to participate in the NOPR. The Indications table lists the cancers and indications that will be accepted in the Registry.

PET Facility Responsibilities

The PET facility is responsible for collecting and entering patient data into the Registry database through a web application at www.CancerPETregistry.org. Below is a brief summary of the data collection procedure.

- When a patient eligible for entry into the NOPR presents at the PET facility, the facility contacts the referring physician and obtains confirmation that the referring physician will submit the pre- and post-PET data requirements.
- The facility registers the patient on the NOPR via a Web form, at which time a Registry case number is assigned.
- The NOPR will e-mail confirmation to the PET facility and at the same time e-mail a request for the pre-PET form to the PET facility for delivery to the referring physician.
- The referring physician must complete and return the Pre PET Form to the PET facility and the PET facility must enter the Pre PET Form into the NOPR database by midnight of the day of the PET scan.
- At some time before the PET study, or when the patient arrives for the PET scan, the PET facility will provide the patient with the ACR IRB-approved standard NOPR Patient Information Sheet that is posted on the NOPR Web site. The patient will be able to contact the NOPR directly for more information, if necessary. The patient will indicate his or her consent verbally to staff at the PET facility, either on the day of the PET study or within two working days after the PET study is completed. Written consent is not required. The PET facility will note in the database and on the PET Report Form, if the patient gave or withheld consent for use of his or her data in future NOPR research.
- After the PET scan is performed, the PET facility sends the PET report to the referring physician, enters the study completion date into a Web form, and submits the report text electronically to the NOPR database. Note that the PET scan must be completed and the PET Scan Completion Form must be entered into the database within 14 days of case registration or the case will be marked as ineligible.
- After the PET Scan Report Form is entered, the database will send the PET facility a patient-specific Post PET Form for delivery to the referring physician. This form will also include an ACR IRB-approved Referring Physician Information Sheet. The physician will indicate on the Post-PET Form whether consent for use of the response data in future NOPR research has been given or withheld. All data will be sent to CMS, but the dataset used by NOPR investigators for research will contain only the data of patients and physicians when both have consented to have the data included. This form must be completed, returned to the PET facility, and entered into the NOPR database within 30 days of the PET scan.

Referring Physician's Responsibilities
The patient's referring physician must agree to complete pre- and post-PET data collection forms consisting of approximately 5 questions regarding the patient's planned management.

- The Pre-PET Form must be completed by the referring physician and returned to the PET facility prior to the patient's PET scan. A blank Pre PET Form can be downloaded from the NOPR Web site and sent to the PET facility at the time of patient referral. If the form is not submitted with the referral a patient-specific form will be e-mailed to the PET facility for delivery to the referring physician. The Pre-PET Form can be returned to the PET facility via, FAX, mail, or hand delivery.
- After the PET is performed a patient-specific Post PET Form will be e-mailed to the PET facility for delivery to the referring physician for completion within 30 days. This form will also include an ACR IRB-approved Referring Physician Information Sheet. The physician will indicate on the Post-PET Form whether consent for use of the response data in future NOPR research has been given or withheld. All data will be sent to CMS, but the dataset used by NOPR investigators for research will contain only the data of patients and physicians when both have consented to have the data included. This form can also be returned to the PET facility via FAX, mail, or hand delivery.

The case is eligible for CMS reimbursement only if the Pre-PET Form is completed and returned to the PET facility prior to the PET scan and the Post-PET Form is completed and returned within 30 days of the PET scan.

How to Obtain Medicare Reimbursement
The NOPR database will notify the PET facility when all case data have been entered. The PET facility can then bill CMS for the study. The PET facility can check on the case status of their patients at any time via the reporting tools available on the NOPR Web site.

Sponsored by:

- Academy of Molecular Imaging

Endorsed by:

- American College of Radiology
- American Society of Clinical Oncology
- Society for Nuclear Medicine

Managed by:

- American College of Radiology
- American College of Radiology Imaging Network

Advisor:

- Centers for Medicare & Medicaid Services

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PET Fancy

For treatment planning and evaluation of tumor response, radiation therapy departments are turning to PET and PET/CT.

By Sasa Mutic, MS

Volumetric patient imaging has become a cornerstone of modern radiation therapy practice, with its uses ranging from treatment planning to tumor detection and staging, and from daily patient positioning to evaluating treatment efficacy, outcomes and complications. These roles help define the ultimate goals of imaging in RT: to anatomically delineate and biologically characterize a tumor, select an appropriate therapy and predict tumor response as early as possible.

To accomplish these goals, RT must use both anatomical and biological imaging. Anatomical imaging delineates normal organs and tumors to the extent that they're anatomically visible on an image. Computed tomography (CT) and magnetic resonance imaging (MRI) are the main sources of anatomical imaging in RT. Biological imaging, on the other hand, doesn't need to indicate gross, anatomically visible changes; rather, it must capture information regarding a tumor's underlying physiology, metabolism, function and molecular makeup. No single imaging modality can accomplish all these goals, and RT patient management can involve CT, positron emission tomography (PET), MRI, single photon emission computed tomography (SPECT), ultrasound and planar radiography. Rather than compete, these imaging modalities are used in a complementary manner, and optimal patient treatment may require studies from several of these techniques.

PET's rise in RT

Biological imaging in RT has grown rapidly in recent years, fueled by reports that imaging functional and biological tumor properties could improve disease detection, staging, treatment modality selection (intramodality and intermodality), target volume definitions, treatment planning, and outcome estimation and patient follow-up. PET, SPECT and MRI provide biological imaging information for RT treatment planning. In recent years, fluorine-18 fluorodeoxyglucose-based PET has become RT's main source of biological imaging information, and PET's increased usage in RT far outpaces MRI, SPECT and ultrasound. While the greatest advantage of FDG-based PET thus far has been improved staging, several reports also have shown that PET information can alter RT target volumes in approximately 30 percent of patients. Additionally, a concept of biological target volumes has been proposed. BTVs are portions of tumor volumes that have been identified with biological imaging as having increased importance due to properties that make those portions particularly difficult to eliminate. During RT planning, BTVs might receive increased dose and special considerations.

The PET/CT effect

Beside clinical advantages, one main reason for PET's predominance in RT biological imaging has been the development of PET/CT scanners. A common problem with multimodality imaging for RT treatment planning is registration of images that are acquired in different scanners. The PET/CT scanner virtually eliminates this problem, as patients remain in the same position for the PET and CT portions of the scan. Patient movement and breathing motion still exist during image acquisition, and PET/CT registrations aren't perfect. However, these registrations are much more accurate and easier to implement than image registration from stand-alone scanners. Combined PET/CT scanners make biological imaging for RT treatment planning possible in routine clinical practice.

Many RT departments now house RT-dedicated PET/CT scanners or scanners that are shared between RT and nuclear medicine departments. Recognizing RT's demand for imaging studies, major imaging equipment manufacturers have made commercially available scanners designed for RT or possessing features designed for RT. This represents a paradigm shift from the 1980s and 1990s, when scanners were manufactured specifically

for diagnostic imaging, and any use for RT imaging required design modifications, often by the user. This change in the manufacturer's view of RT imaging is evident in the development of large-bore CT scanners—a segment of CT technology designed specifically for RT. This customization of imaging equipment also carried over to the design of PET/CT scanners, which are being equipped with tools common to CT simulators (flat tabletops, external lasers, respiratory gating, specialized virtual simulation software, etc.). These features allow PET/CT scanners to be installed in lieu of CT simulators, giving rise to the concept of the PET/CT simulator.

PET on the move

Obviously, PET imaging for diagnosis and staging will remain with nuclear medicine facilities. However, PET scans for treatment planning and evaluation of tumor response during treatment could move to RT departments. Sound farfetched? Consider the fact that, not long ago, CT scanners were located mainly in diagnostic radiology, where most RT CT imaging was performed.

Clearly, PET's full potential in RT isn't yet fully understood. As additional studies are conducted and imaging equipment is improved further, the scope of PET imaging's influence on RT will become clearer. Current experience, however, suggests that an important segment of our patient population will require PET imaging for adequate management.

Sasa Mutic, MS, is an associate professor of radiation oncology and chief of clinical physics service in the department of radiation oncology at Siteman Cancer Center, Mallinckrodt Institute of Radiology, Washington University School of Medicine, St. Louis.

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Technology and Equipment Committee Meeting

August 29, 2007

Positron Emission Tomography (PET) Scanner Material

Comments Related To

PET Petition: The Presbyterian Hospital

Proposed 2008 State Medical Facilities Plan
Public Hearing – August 1, 2007

Public Hearing Comments on Behalf of The Presbyterian Hospital
Wallace C. Hollowell, III

- Good afternoon. My name is Chuck Hollowell. I am an attorney with the law firm Nelson Mullins Riley & Scarborough, L.L.P. I am speaking today on behalf of The Presbyterian Hospital.
- Presbyterian submitted a petition for an adjustment to the PET scanner need determination in the Proposed 2008 State Medical Facilities Plan ("SMFP") at the July 25, 2007 public hearing in Charlotte.
- Today's remarks are made in support of this petition by Presbyterian.

- The need methodology for additional PET scanners in the Proposed 2008 SMFP provides that a need for an additional PET scanner is recognized when an existing fixed PET scanner is utilized at or above 80% of capacity, which has been set at 2,600 procedures per year. This means that a need is triggered when a fixed PET scanner is utilized at least 2,080 procedures per year.
- The time period used to make this calculation is the 12 month period reflected in the 2007 Hospital Licensure Applications – the 12 months ending September 30, 2006.
- Based on this 12 month period, Presbyterian's utilization rate for its PET scanner was 1,988 procedures, or 76.46% of capacity.
- This was only 92 procedures – or 3.5% – short of triggering a need for an additional PET scanner in HSA III.

- Presbyterian's PET utilization continues to grow rapidly.
- As shown in the materials submitted to the SHCC with Presbyterian's petition, for the 12 months ending November 30, 2006 – just *two months* beyond the data used in the Proposed 2008 SMFP – Presbyterian's PET scanner was used for 2,095 procedures, or 81% of capacity.
- For the 12 months ending December 31, 2006 – just *three months* beyond the data used in the Proposed 2008 SMFP – Presbyterian's PET scanner was utilized for 2,128 procedures, or 102% of capacity.
- Thus, if the standard need methodology is applied to data that is more current by only two or three months, then Presbyterian's utilization of its PET scanner clearly establishes a need for an additional PET scanner in HSA III.

- Presbyterian's PET utilization is not only strong, but shows every indication that it will continue to increase.
- As set forth in detail in the materials submitted with Presbyterian's petition:

    - Presbyterian's average number of PET scans per month has increased each year since Presbyterian began providing PET services in October 2004;
    - Table 9K in the Proposed 2008 SMFP shows that Presbyterian ranks *third* out of 22 facilities in the State with PET scanners in terms of PET scanner utilization;
    - The Proposed 2008 SMFP recognizes that "the clinical use of PET scanning is increasing rapidly, and the new applications involve the diagnosis of cancer;"
    - It appears likely that other PET codes will be added for reimbursement, such as those for cancer treatment monitoring and re-staging of cancer recurrence; and
    - Table 9G in the Proposed 2008 SMFP shows that Presbyterian ranks *in the top ten* out of 64 facilities in the State providing radiation oncology service in the number of procedures performed.

- Thus, Presbyterian currently has one of the highest rates of utilization of its existing PET scanner of any scanner in the State, and this utilization is only expected to increase given the Presbyterian's robust cancer treatment program and the increasing number of cancer-related PET applications.

- Need determinations in the SMFP are not simply mathematical exercises. This is why the Proposed SMFP is published for public comment and why the SHCC considers petitions for adjustments to particular need determinations.
- Once the standard methodology has been applied to a snapshot of data from a particular time period, providers are allow to submit petitions to adjust the need determination based on other information that was not captured in the standard methodology and the data snapshot from a particular time period.

- Presbyterian's utilization numbers set forth in the Proposed 2008 SMFP show that it barely missed generating a need for an additional PET scanner in HSA III. These utilization numbers were based on a 12 month period that ended September 30, 2006.
- By looking at utilization data that is only two to three months more current, Presbyterian's utilization of its existing PET scanner easily generates a need for an additional PET scanner in this HSA.
- There are strong indications that Presbyterian's utilization of its PET scanner will only continue to increase.
- There is no reason why the SHCC should not consider this more current utilization data from Presbyterian. In fact, this petition process is explicitly designed so that this type of updated information from a particular hospital can be taken into account.

- As a result, Presbyterian respectfully requests that the SHCC consider the updated data regarding Presbyterian's utilization of its PET scanner and adjust the need determination in the Proposed 2008 SMFP to include the need for one additional PET scanner for HSA III.

Survey: PET Scanner Weekly Hours of Operation
July 2007

	Hours of Operation	***Hours Per Week***
Carolinas Medical Center Charlotte	Monday - Friday 8:30 a.m. - 5:00 p.m.	42.5
Duke University Medical Center	Monday - Friday 6:30 a.m. - 6:30 p.m.	60
Forsyth Medical Center	Monday - Friday 6:30 a.m. - 11:00 p.m.	82.5
Pitt County Memorial/ECU	Monday - Friday 7:00 a.m. - 4:30 p.m.	42.5
The Presbyterian Hospital	Monday - Friday 6:30 a.m. - 5:30 p.m.	55
WFU/North Carolina Baptist Hospital	Monday - Friday 7:00 a.m. - 4:00 p.m.	40
UNC	Monday - Friday 7:00 a.m. - 4:00 p.m.	40
High Point Regional Medical Center	Monday - Friday 7:00 a.m. - 5:00 p.m.	50
PET CON Regs at 10A NCAC 14C.3702(b)(3)(B)	Six Days Per Week 12 Hours Per Day	72
MRI CON Regs at 10A NCAC 14C.2702(c)(2)	66 Hours Per Week	66
Mobile MRI CON Regs at 10A NCAC 14C.2702(c)(3)	40 Hours Per Week	40
CT Scanner CON Regs at 10A NCAC 14C.2303(k)	66 Hours Per Week	66
Linear Accelerator CON Regs at 10A NCAC 14C.1902(b)(4)	35 Hours Per Week	35
Operating Room CON Regs at 10A NCAC 14C.2103(a) & SMFP	5 Days Per Week 9 Hours Per Day	45

PET Data Sources: Dr Coleman's Letter (DUMC), PET Supervisors & Techs, CMC web site
File: PETScannerHoursOfOperation.07.31.2007.xls

2008 Proposed SMFP Public Hearing
July 25, 2007---1:30 PM, Charlotte NC

Presbyterian Hospital: Request for Adjusted Need Determination to Add One New PET Scanner for HSA III in the Proposed 2008 SMFP

Hearing Remarks of Robert Quarles, M.D.
Nuclear Medicine and PET Medical Director, Department of Radiology
Presbyterian Hospital, Charlotte, NC
Board Certified Radiologist, Mecklenburg Radiology Associates

- I have been involved with PET technology since 1987-1988 and it is the single most important tool to be developed in nuclear medicine in this generation

- PET is essentially a scan performed using a radioactively labeled sugar as the imaging agent. Because cancer cells consume a large amount of sugar, the PET can detect and then pinpoint the tumor more effectively than any other imaging modality.

- The Presbyterian Hospital PET scanner has undergone a rapid ramp up since it became operational in October 2004, experiencing growth of 18 to 20 percent annual growth in PET scans when comparing the first 6 months to the first six months of 2007. Please refer to the exhibits enclosed that highlight the extent of growth in PET scans at Presbyterian Hospital.

- In projecting the need for a second PET scanner at Presbyterian, 2 percent growth factor per quarter was utilized or approximately 10 percent on an annual basis. This is very conservative given the actual annual growth rate of 18 20 percent since PET services began.

- If Presbyterian Hospital must wait beyond the 2008 CON Plan year to seek the state's approval for an additional PET scanner, we project that the single PET scanner at TPH will be performing 2,600 to 2,900 PET scans per year. This is well beyond the practical limits of the capacity of a single PET scanner.

- Based on actual PET volumes and anticipated growth, Presbyterian will need to file a CON application in mid 2008 in order to go through the CON process and ensure that a second PET scanner comes on line to meet increased the increased demand and avoid an unacceptable bottleneck in access to diagnostic PET studies for our patients and their referring physicians. Therefore, we are seeking in the 2008 SMFP a need determination for one new PET scanner in HSA III now, so that patient access and quality of care can be maintained.

- The Presbyterian Cancer Center is one of the ten busiest cancer centers in the state with Duke, Forsyth Medical Center, and Moses Cone Health System making up the top three. Over 95 percent of the scans done at Presbyterian Hospital are cancer related.

2008 Proposed SMFP Public Hearing
July 25, 2007---1:30 PM, Charlotte NC

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- Presbyterian Hospital will implement a third linear accelerator in Ballantyne n 2008 which will significantly increase radiation therapy treatments. This will add to the need and demand for PET services related to cancer services.

- The National Oncologic PET Registry (NOPR) was established in 2005 by the Centers for Medicare and Medicaid Services (CMS) to expand coverage for PET scans with F-18 fluorodeoxyglucose (FDG-18). Currently CMS covers nine cancers and indications for Medicare reimbursement. However, as a result of the NOPR, it is expected that the Medicare coverage will be expanded. Once this occurs more indications for PET diagnostic studies will be eligible for reimbursement. This will also serve to continue the upward trend in the demand for PET diagnostic studies at TPH.

- PET is rapidly becoming the standard of care in cancer services at busy cancer centers like TPH. As the use of PET diagnostic studies in cancer care continues to grow, other diagnostic uses of PET are also expanding. For example, PET is also being recognized as an effective tool in cardiac, Alzheimer's and other areas. Because our scanner is operating close to capacity with a full load of PET diagnostic studies for cancer patients, we lack the necessary flexibility to fully expand PET diagnostic for additional specialties and patients that would benefit. A second PET scanner at TPH would create the necessary additional capacity to allow that growth to occur and be readily accommodated.

File: PETPresbyPetitionRemarksDrQuarlesPublicHr08SMFPCharlotte07 25 2007.doc

2008 Proposed SMFP Public Hearing
July 25, 2007---1:30 PM, Charlotte NC

Presbyterian Hospital: Request for Adjusted Need Determination to Add One New PET Scanner for HSA III in the Proposed 2008 SMFP

Hearing Remarks of Wendy Burkart, BSRT, MHA
Director of Radiology Services
Presbyterian Hospital, Charlotte, NC

- I want to emphasize what Drs. McGinnis and Quarles and Cindi have already commented on and that is the fact that given the current and future PET demands at Presbyterian Hospital, a second PET scanner is a necessity.

- Dr. Coleman of Duke University has been quoted estimating that the demand for PET services will increase at a rate of 15 percent per year. With double digit growth in this modality, Presbyterian Hospital will be unable to accommodate the growth, not will we be positioned to accommodate new applications emerging in cardiology and neurology.

- The standard of care is transitioning to the use of PET/CT for radiation treatment planning. This process requires 90 minutes of scan/table tie as compare to 30 minutes for PET.CT scan time. This translated to an increased burden on the existing PET scanner.

- As Dr. Quarles stated we are only 4 percent shy of the 2,080 adjusted scan threshold. Our conservative quarterly volume projections indicate Presbyterian's PET growth at 2 percent. This corresponds to the 8 – 10 percent annual growth compared to our actual annual growth of approximately 20 percent since beginning operation in October 2004. Based on these assumptions, PET volumes will range from 2,600 to 2,900 by the end of calendar year 2009 – well beyond the current threshold of 2,080.

- In addition, Presbyterian Hospital is currently above the 12,500 radiation treatment threshold at 16,659. Accordingly Presbyterian Hospital will implement a third linear accelerator in 2008. Cancer services continue to expand within the Presbyterian system and PET scans are an essential element in the diagnosis, staging, and treatment of a variety of cancers.

- These factors coupled with Presbyterian Hospital's strong growth necessitate additional PET technology in HSA III for 2008. If a need is determined in 2008, the PET scanner will not become operational until 2009 when our volume projections indicate we will be performing well over the state threshold.

File: PETPresbyPetitionRemarksBurkartPublicHR08SMFPCharlotte 07 25 07.doc

2008 Proposed SMFP Public Hearing
July 25, 2007---1:30 PM, Charlotte NC

Presbyterian Hospital: Request for Adjusted Need Determination to Add One New PET Scanner for HSA III in the Proposed 2008 SMFP

Hearing Remarks of Cindi Gilbert, BHS, CNMT, PET, RT(N)
Supervisor of PET Services
Presbyterian Hospital

- FDG-18 is the radioactive dose injected into the patient in order to find "hot spots" typical of cancer in the human body.

- This radioactivity decays very quickly and cannot be stored for later use. Currently our doses come to us from 1 ½ hours away

- The radioactivity is ordered per patient by the patient's weight, type of PET scan, and time of injection. So if a patient is late or not prepared for the scan the dose is wasted..

- Our doses come as unit doses, one dose per patient drawn up in a syringe, and not a bulk multi-dose vial. We are not equipped with robotic arms to draw up these doses from a multi-dose vial plus the radiation burden to the technologists would reach upper ALARA limits.

- The commercial suppliers of the FDG-18 do not make the doses past late morning so to get additional doses for later in the day scanning is extremely difficult and not cost effective. This would cause major financial and staffing changes for the commercial suppliers as well. These vendors may not be willing to provide service for one hospital. We are currently under contract with a vendor and are at its mercy.

- FDG suppliers cannot be expected to operate past normal operating hours in order to be cost effective therefore it is not feasible to arbitrarily expand the PET operating hours. Additionally patients already compromised by cancer or undergoing treatment cannot be expected to undergo scans at late or very early hours outside of the norm.

- Even if we were to somehow able to access doses for the afternoon and have them delivered in the morning, the hot lab would have unacceptably high radioactive levels for the staff.

- Unlike the academic centers that have a cyclotron in their institutions, we cannot make FDG-18 as needed. Plus we absorb the cost of each dose not utilized. This makes us different than academic institutions.

- We could purchase a cyclotron for $2.3 million, fit it with the USP-797 clean room regulations, and bring in a radiopharmacist to make the doses and an engineer to run it. With this idea, losing a dose or two per day would not be an issue as it is for the clinical institutions. However, a cyclotron is not cost-effective in clinical facilities like Presbyterian.

Presbyterian Hospital: Request for Adjusted Need Determination to Add One New PET Scanner for HSA III in the Proposed 2008 SMFP

(Cindi Gilbert Remarks continued)

- Our patients arrive; thirty minutes apart, they are injected with radioactivity, wait 90 minutes for FDG uptake, and are scanned approximately 30 minutes typically. The uptake time protocol is the same as Duke University's.

- With that information in mind, knowing that the limiting factors of FDG availability, other work flow barriers include patients arriving to the department late (the dose has decayed to a point it is unusable and very ill patients being injected in a timely fashion. Diabetic patients whose blood glucose level is elevated must have their scans canceled as well as patients arriving that are non-prepped. Again, we absorb the cost of these doses.

- We try very hard to obtain patient information prior to the patient's arrival but this is not always successful.

- When a radiation therapy patient arrives, I block the schedule so the next two patients coming in are an hour after the radiation therapy patient. This patient's scan takes up almost three times the amount of time that a traditional oncology patient takes. These issues create a work flow barrier to our institution.

- Presbyterian Hospital's PET is staffed from 6:30 AM to 6 PM Monday through Friday. Patients are scheduled from 7 AM to 5 PM. These operating hours are consistent and reasonable compared with other NC PET scanners facilities. Only mobile PET vendors operate on weekends.

- The American College of Radiology (ACR) will request CMS to consider reimbursing for other cancers immediately following ASNC in November. A decision should come from CMS within 6 months.

- Also CMS is currently reviewing an indication for PET reimbursement. This is for fever of unknown origin (FOU). A decision should be made within the next few months. As the Medicare reimbursement expands and other payers follow, PET service demand and volumes will only increase putting more strain on the one scanner at Presbyterian Hospital. A second scanner is necessary to meet our immediate need as well as the projected cancer and other specialty indications expected in the near future.

File: PETPresbyPetitionRemarksCindiGilbertPublicHR08SMFPCharlotte 07 25 2007(2).doc

2008 Proposed SMFP Public Hearing
July 25, 2007---1:30 PM, Charlotte NC

Presbyterian Hospital: Request for Adjusted Need Determination to Add One New PET Scanner for HSA III in the Proposed 2008 SMFP

Hearing Remarks of L. Scott McGinnis, M.D.
Radiation Therapy Medical Director, Presbyterian Cancer Center
Presbyterian Hospital, Charlotte, NC

- PET is crucial to oncology services as the most accurate technology available to pinpoint and target tumors. Since many tumors are undetectable on routine imaging equipment, PET has the unique ability to scan and detect cancer at a molecular level. Early detection and thus earlier treatment results in better outcomes.

- Beyond the diagnosis, PET can be used in radiation therapy and in the ongoing assessment of therapy and in determining the need or result of surgery. PET usage lowers the need for additional surgeries, chemotherapy or radiation therapy with its more precise imaging.

- PET technology fused with CT scanning capabilities is an important aspect in cancer services. Integrated PET technology has been one of the most significant advances in diagnostic imaging in the past decades.

- PET/CT technology improves outcomes as the tumor is targeted as a "hot spot" allowing noncancerous tissue to remain undamaged during the radiation therapy. This leads to better quality treatment with increased patient benefit.

- PET is the leading tool in use with Tumor Boards and in conjunction with Presbyterian's Multidisciplinary Clinics that currently involve breast, GI, melanoma and prostate cancers.

- The Presbyterian Hospital PET scanner is at capacity and is experiencing an increase of 10 – 15 percent over the past five years. At this rate of growth, without consideration of new clinical applications or increased reimbursement coverage, Presbyterian Hospital's PET scanner will be operating at more than the state threshold by 2009.

- To promote access and to remain efficient in providing quality diagnostic and treatment options, a second PET scanner is necessary at Presbyterian Hospital. The increased use of PET in radiation therapy planning consumes more time than a diagnostic PET scan – almost triple the time. In order to accommodate the use o PET diagnostics for superior radiation therapy treatment planning while continuing to meet the ongoing demand for diagnostic PET scans, another PET scanner would prove more cost-effective while meeting the needs of our cancer patients.

2008 Proposed SMFP Public Hearing
July 25, 2007---1:30 PM, Charlotte NC

Presbyterian Hospital: Request for Adjusted Need Determination to Add One New PET Scanner for HSA III in the Proposed 2008 SMFP

- The Presbyterian Cancer Center is one of ten busiest cancer centers in North Carolina. This fact, in addition to a third linear accelerator to begin operating in 2008 will only increase the demand for PET diagnostic services at Presbyterian.

File: PETPresbyPetitionremarksDrMcGinnisPublicHr08SMFPCharlotte 07 25 2007.doc

Top of Document

Technology and Equipment Committee Meeting

August 29, 2007

Positron Emission Tomography (PET) Scanner Material

Comments Related To

PET Need Determination in Proposed 2008 SMFP: Forsyth Medical Center

COMMENT TO THE NORTH CAROLINA STATE HEALTH COORDINATING COUNCIL REGARDING THE NEED DETERMINATION FOR POSITRON EMISSION TOMOGRAPHY SCANNERS IN THE 2008 STATE MEDICAL FACILITIES PLAN

Forsyth Medical Center ("Forsyth") submits this comment to the North Carolina State Health Coordinating Council ("SHCC"), in support of the need determination contained in the Proposed 2008 State Medical Facilities Plan ("SMFP") at Table 9M, page 122, for a fixed dedicated positron emission tomography ("PET") scanner in Health Service Area ("HSA") II.

Forsyth is a non-profit corporation operating a full service hospital in Winston-Salem with 751 licensed acute care beds. Forsyth offers a comprehensive cancer program with four linear accelerators currently in operation. As shown in the Proposed 2008 SMFP, Forsyth provided 28,435 radiation oncology procedures in the most recent annual period for which information is available.

Forsyth may be contacted about this Comment directly or through its counsel, at the following addresses:

Novant Health, Inc.
Forsyth Medical Center
Gregory J. Beier, President
3333 Silas Creek Parkway
Winston-Salem, NC 27103
Telephone: (336) 718-2015
gjbeier@novanthealth.org

Nelson Mullins Riley & Scarborough LLP
Noah H. Huffstetler, III
Counsel for Novant Health and
Forsyth Medical Center
4140 Parklake Avenue, Suite 200
Raleigh, NC 27612
Telephone: (919) 877-3801
noah.huffstetler@nelsonmullins.com

On page 121, the Proposed 2008 SMFP provides in pertinent part:

> One additional fixed dedicated PET scanner is needed for each existing fixed PET scanner that was utilized at or above 80% of capacity during the twelve month period reflected in the owner's or operator's 2007 Hospital Licensure Renewal Application on file with the N.C. Division of Facility Services. For the purposes of this determination, the annual capacity of a fixed dedicated PET scanner is (2,600 x .80 = 2,080) procedures. . . .

Applying this methodology, Table 9M on page 122 of the Proposed 2008 SMFP shows a need for one additional fixed PET scanner in HSA II, in which Forsyth is located. For the period covered by its 2007 annual license renewal application, the twelve months ending September 30, 2006, the utilization rate for Forsyth's PET scanner was 2,417 procedures, or 92.96% of capacity. This utilization of Forsyth's equipment based on PET scans per scanner ranks first among the twenty-two facilities in North Carolina with fixed PET scanners.

Moreover, the data set forth in Exhibit A to this Petition shows that the utilization of Forsyth's PET scanner continues to grow rapidly. The growth in Forsyth's PET scanning services is likely not only to continue, but to accelerate. The discussion of PET utilization contained at pages 116-118 of the Proposed 2008 SMFP recognizes "the steady growth in the number of clinical studies for which the Centers for Medicare and Medicaid Services ("CMS") authorizes reimbursement for PET scanning," and concludes that "the clinical use of PET scanning is increasing rapidly, and the new applications involve the diagnosis of cancer." In addition, the CMS National Oncologic PET Registry (NOPR)[1] is tracking data to determine if other PET codes should be added for reimbursement beyond the current codes that focus on PET scans used for initial diagnosis and staging of cancer patients. It is likely that the data will show

[1] Dr. Coleman, Vice Chair, Department of Radiology, Professor of Radiology, Director of Nuclear Medicine, Duke University Medical Center, is Co-Chair for NOPR.

that PET scans for cancer treatment monitoring and re-staging of cancer recurrence should also be added as reimbursable PET scan codes. See Exhibit E. As shown on Table 9G at pages 108-09 of the Proposed 2008 SMFP, Forsyth's radiation oncology service ranks second among the sixty-four facilities providing that service in North Carolina in the number of procedures performed.[2] Given the robust and growing cancer treatment programs offered by Forsyth, and the rapidly increasing number of types of cancer for which PET scanning is useful, it is clear that Forsyth's PET utilization is likely to grow even more quickly in the coming years. This is further substantiated by the letter of Dr. Basile, Medical Director for Inpatient Radiology at Forsyth Medical Center, which is attached as Exhibit B to this Petition.

Despite the clear evidence that an additional PET scanner is needed in HSA II as indicated in the draft 2008 SMFP on page 119, Forsyth is concerned that there may be an attempt to deprive it of the opportunity to apply for a certificate of need to acquire the needed equipment. At the May 16, 2007 meeting of the SHCC's Technology and Equipment Committee, it was suggested that the threshold to trigger a need determination for an additional PET scanner should be raised to 2,500 procedures or more per year[3]. Moreover, Forsyth has received notice that a "PET Scanner Discussion Group Meeting" has been scheduled for August 15, 2007. For all of the reasons set forth below, no attempt should be made to change the statewide methodology for making PET scanner need determinations in the 2008 SMFP.

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[2] As measured by ESTV-weighted radiation therapy treatment procedures: (1) Duke @ 36,634; (2) FMC @ 28,435; (3) Moses Cone Health System @ 28,362; (4) Cape Fear Valley Medical Center @27,631; (5) First Health Moore Regional @ 23,764; (6) UNC Hospitals @ 22, 224; (7) Mission Hospitals @ 20,776; (8) NCBH @ 20,251; (9) Catawba Valley Medical Center @ 20,766; (10) The Presbyterian Hospital @ 16,659. See Exhibit D.

[3] Based on a discussion at the May 16, 2007 meeting of the SHCC's Medical Equipment and Technology Committee. The Chair of the Committee discussed a letter from Dr. Coleman at Duke University Medical Center DUMC) that stated "our experience suggests that the capacity of a fixed dedicated PET CT scanner is 15 procedures a day…If 15 per day were capacity, a fixed dedicated PET CT scanner could provide 3,750 procedures per year (15 X 250). Given the length of time required to bring an additional machine on line, I would make the threshold a volume of 10 procedures per day or 2,500 per year." See Exhibit C for a copy of Dr. Coleman's letter. An additional calculation shows that the 2,500 PET procedures year threshold is 67% of 3,750 PET procedures year assumed annual capacity.

First, the Agency's performance standards codified at 10A N.C.A.C. 14C.3703 require an applicant proposing to acquire a PET scanner to demonstrate that "its existing dedicated PET scanners . . . performed an average of at least 2,080 PET procedures per PET scanner in the last year."[4] If the proposed change in the 2008 SMFP were adopted, the 2,080 procedure threshold would be accordingly adjusted to 2,500 procedures, and should be applicable to any future application for new or replacement equipment. Because the cost of PET equipment typically exceeds $2,000,000, a CON is normally required to replace an existing scanner. For example, during 2007 Duke University Medical Center submitted a CON application to replace a PET scanner with a new PET/CT scanner and the associated project capital cost was $3.7 Million (Project I.D. # J-7794-07); the project was approved under the 2,080 utilization standard. Therefore, if the threshold for a PET scanner need determination is raised to 2,500 procedures[5] per year, many existing providers of PET scanning services will be unable to replace their existing equipment when it reaches the end of its useful life, if they are not able to establish that the annual utilization of their PET scanner will exceed the new higher volume threshold of 2,500 PET procedures per year. Furthermore, the PET need method does not include any weighting factors for PET procedures (as the MRI and CT scan regulations and need method do), so this would make it even more difficult for all applicants seeking to replace and update original PET and PET/CT scanners to demonstrate the need in a CON application. Moreover, any attempt by

[4] The 2,080 PET procedures/year threshold is 80% of the annual capacity of a PET scanner 2,600 PET procedures/year. (= 2,600 X .80 = 2,080). This PET scanner capacity definition and utilization threshold to trigger need for a new PET scanner is found in the 2007 SMFP at page 115 and in the draft 2008 SMFP at page 121.

[5] Based on a discussion at the May 16, 2007 meeting of the SHCC's Medical Equipment and Technology Committee. The Chair of the Committee discussed a letter from Dr. Coleman at Duke University Medical Center (DUMC) that stated "our experience suggests that the capacity of a fixed dedicated PET CT scanner is 15 procedures a day…If 15 per day were capacity, a fixed dedicated PET CT scanner could provide 3,750 procedures per year (15 X 250). Given the length of time required to bring an additional machine on line, I would make the threshold a volume of 10 procedures per day or 2,500 per year." See Exhibit C for a copy of Dr. Coleman's letter. An additional calculation shows that the 2,500 PET procedures/year threshold is 67% of 3,750 PET procedures/year assumed annual capacity.

the Certificate of Need Section to exempt a certificate of need application to replace existing equipment from the new standard would arbitrary and capricious, and therefore subject to legal challenge.

Second, the argument for raising the assumed capacity is premised in part on the current requirement in 10A N.C.A.C. 14C.3702(b)(3)(B) that a PET scanner be operated for "a minimum of twelve hours per day, six days a week." However, the seventy-two hours of weekly operation required for a PET scanner is inconsistent with the sixty-six hours per week required for similar technologies like a MRI scanner, under 10A N.C.A.C. 14C.2702(c)(1), and a CT scanner, under 10A N.C.A.C. 14C.2302(k). A PET scanner should not be expected to operate more weekly hours than those other diagnostic modalities. This point is reinforced by the views expressed in the letter attached as Exhibit B, in which Dr. Basile maintains that it is unreasonable to expect a PET scanner to be operated as many hours per week as a CT or MRI unit[6].

Finally, it is procedurally inappropriate to implement a fundamental change in a methodology for the 2008 SMFP having statewide implications in a specially convened August 15th, 2007 meeting of a "Discussion Group." As explained on page 7 of the 2007 SMFP:

> Persons who wish to recommend changes that may have a statewide effect are asked to contact the Medical Facilities Planning staff as early in the year as possible, and to submit petitions no later than **March 7**. Changes with the potential for a statewide effect are the addition, deletion, and revision of policies and revision of the projection methodologies. These types of changes will need to be considered in the first four months of the calendar year as the "Proposed SMFP" ... is being developed.

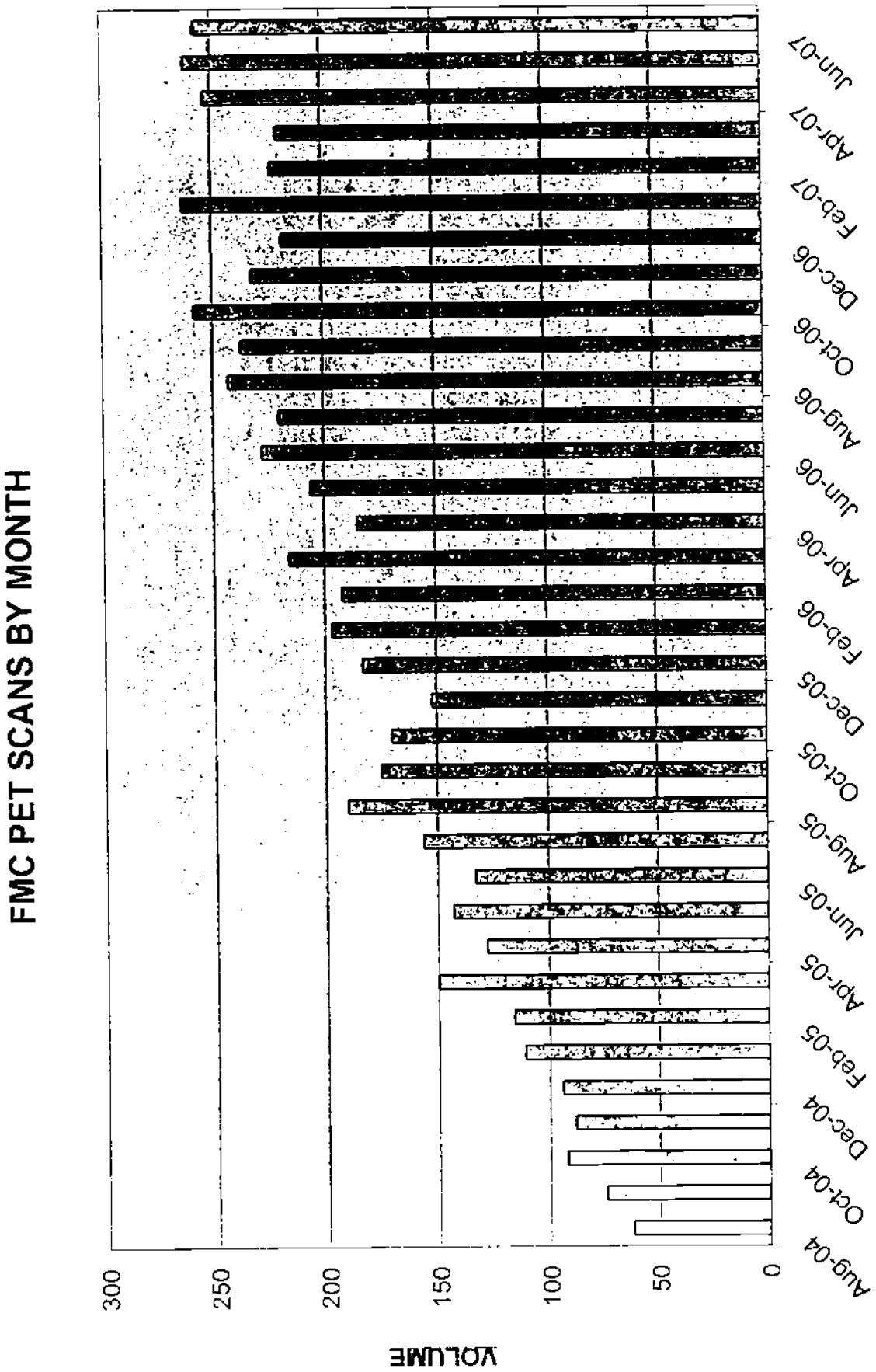
[6] Dr. Coleman's May 2007 letter to the SHCC's Medical Equipment and Technology Committee suggests that, at that time, the DUMC PET/CT scanner was operated 12 hours per day on weekdays (Monday – Friday) or 60 hours per week.

Any such change could first be considered by the full SHCC at its September meeting, after the "Public Review and Comment Period" which includes six public hearings conducted throughout the State on the Proposed 2008 SMFP, and which concludes on August 3, 2007. To change a statewide methodology after any opportunity for public comment on the 2008 SMFP has ended would clearly violate the established procedures for the annual update of the SMFP. Thus, the earliest such a change could properly be implemented is in the 2009 SMFP.

Given the foregoing considerations, Forsyth respectfully submits that the 2008 SMFP should include a determination that an additional fixed dedicated PET scanner is needed HSA III, and that any proposal to change the statewide methodology for making such need determinations should be considered in accordance with the established State Health Planning Process for possible inclusion in the 2009 SMFP.

File: PETCommentFMCToSHCC08ProposedSMFP.07.20.07.doc

EXHIBIT A



FY04 PET Scans = 130
FY05 PET Scans = 1579
FY06 PET Scans = 2,417
FY07 PET Estimated = 2,914 (based on 9 Months of Data)

EXHIBIT A

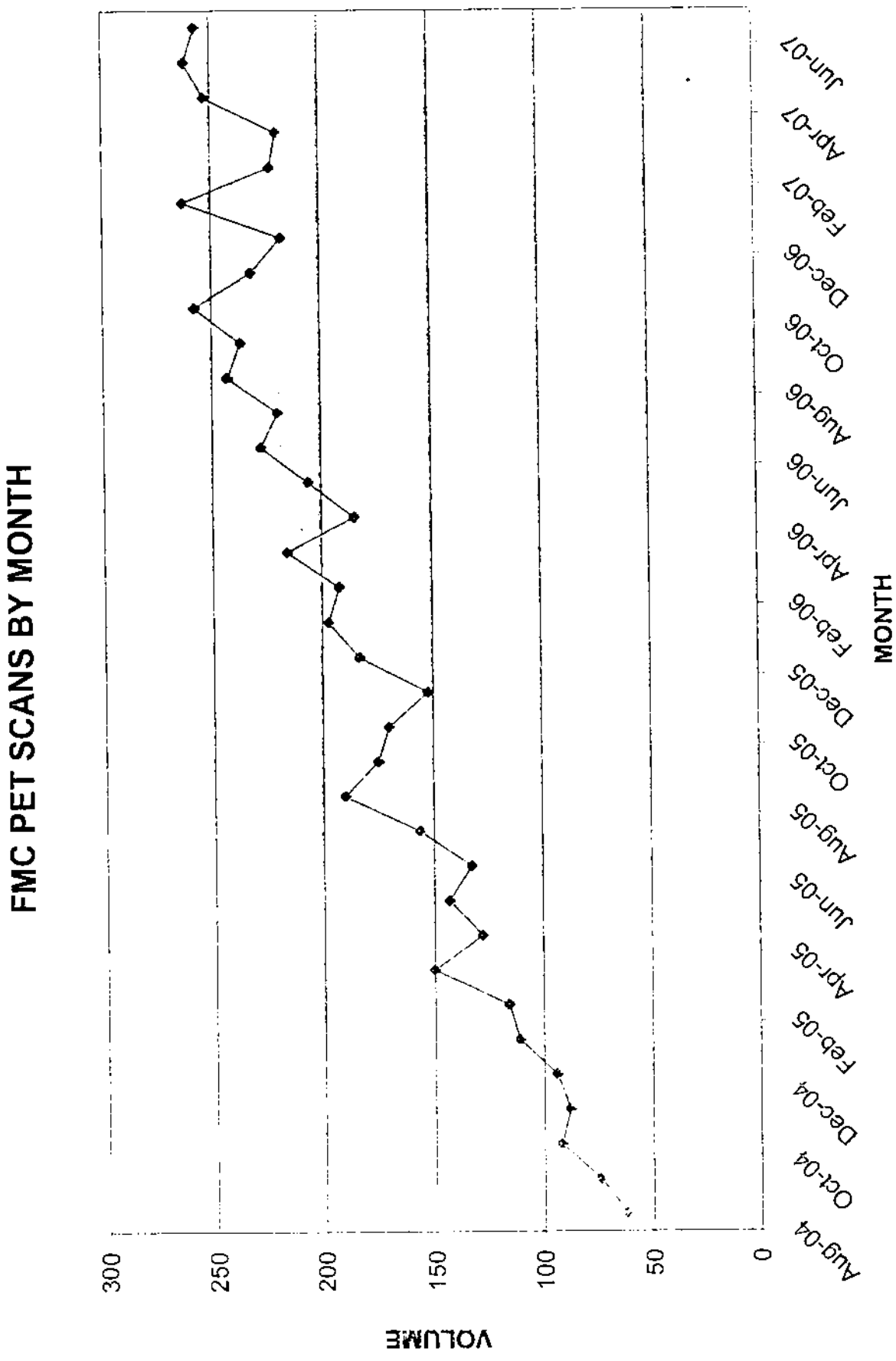

FMC PET SCANS BY MONTH
VOLUME
300
250
200
150
100
50
0
MONTH
Aug-04
Oct-04
Dec-04
Feb-05
Apr-05
Jun-05
Aug-05
Oct-05
Dec-05
Feb-06
Apr-06
Jun-06
Aug-06
Oct-06
Dec-06
Feb-07
Apr-07
Jun-07

Exhibit A

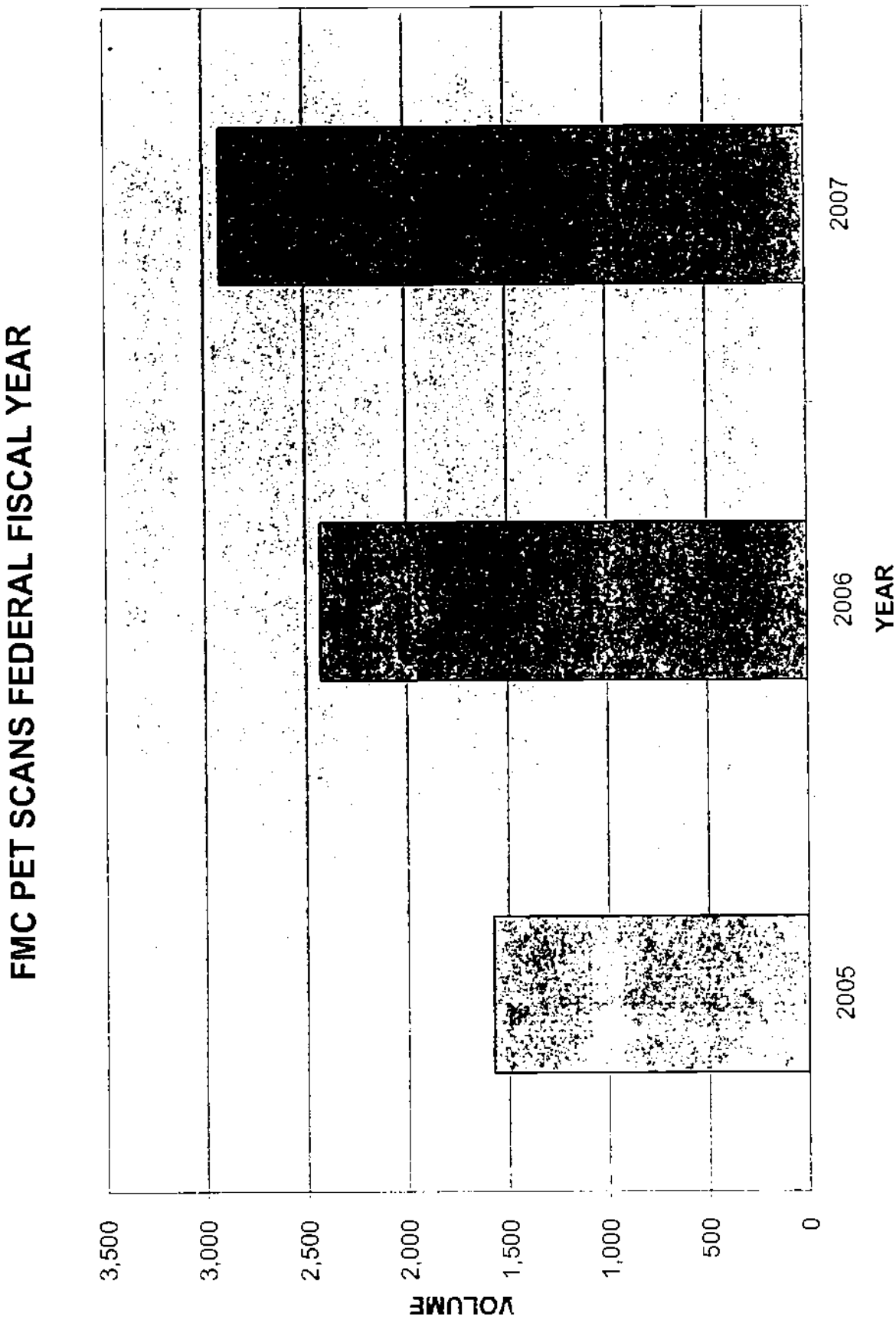

FMC PET SCANS FEDERAL FISCAL YEAR
VOLUME
3,500
3,000
2,500
2,000
1,500
1,000
500
0
2005
2006
2007
YEAR

EXHIBIT B

Forsyth MEDICAL CENTER

July 19, 2007

Chris Ullrich, M.D., Chair
Medical Equipment and Technology Committee
State Health Coordinating Council
701 Barbour Drive
Raleigh, NC 27603

Subject: Comment to the State Health Coordinating Council Regarding the Need Determination for One New PET Scanner for HSA II in the Proposed 2008 State Medical Facilities Plan

Dear Dr. Ullrich:

I support of the Need Determination for a fixed dedicated positron emission tomography (PET) scanner in Health Service Area (HSA) II contained in the Proposed 2008 State Medical Facilities Plan (SMFP). An additional scanner is needed as PET services will clearly continue to grow.

Forsyth Medical Center (FMC) began offering PET services in August 2004 and since then we have completed over 6000 exams. As shown below, the average number of exams per month has increased steadily and is currently almost 250 per month. Over 90% of these exams have been completed on oncology patients. FMC's Derrick L. Davis/Forsyth Regional Cancer Center is the second busiest cancer center in the state second only to Duke, when measured by the number of ESTV radiation therapy treatments offered during FFY 2006 as reported in the proposed 2008 SFMP. FMC's oncology program has experienced sustained growth over the past several years and this growth is expected to continue. Thus a second PET scanner will become necessary not only to keep up with the growing demand from cancer physicians and their patients, but also to allow the expansion of FMC's PET studies to additional specialists and their patients.

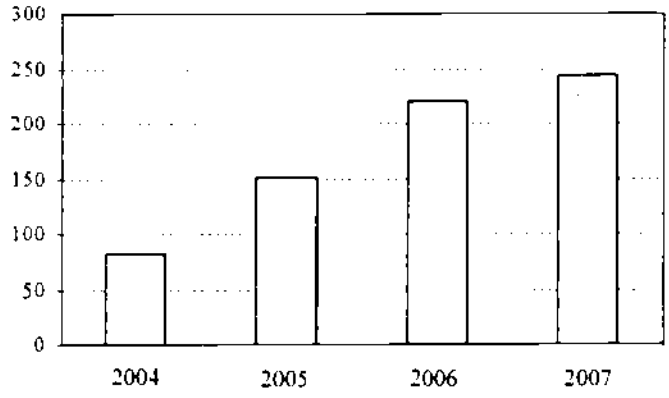


Figure 1. Average number of PET exams per month for each year that PET has been available at Forsyth Medical Center, Winston-Salem, NC.

[1] Based on ESTV-weighted radiation therapy procedures report in the Proposed 2008 SMFP: (1) Duke at 36,634; (2) FMC at 28,435; (3) Moses Cone Health System at 28,362; *4) Cape Fear Valley Medical Center at 27,631; (5) First Health Moore Regional at 23,764; (6) UNC Hospitals at 22, 224; (7) Mission Hospitals at 20,776; (8) NCBH at 20,251; (9) Catawba Valley Medical Center at 20,766; (10) The Presbyterian Hospital at 16,659.

With regard to PET growth, the National Oncologic PET Registry (NOPR) was established in 2005 in response to a proposal by the Centers for Medicare and Medicaid Services (CMS) to expand coverage for PET with F-18 fluorodeoxyglucose (^{18}FDG) to include cancers and indications not presently eligible for Medicare reimbursement. Prior to May 2006 when the NOPR began registering patients to capture data on additional oncologic indications for the use of PET scans, CMS paid for PET scans for only nine types of cancer. The attached table from the NOPR website (http://www.cancerpetregistry.org) shows the types of cancers and indications for which PET scans are already covered by Medicare (designated with a "C"). It also shows the additional cancers and indications for which Medicare reimbursement is available through the NOPR (designated with a "√") if the patient's referring physician and the provider submit data to the clinical registry to assess the impact of PET diagnostic information on cancer patient management. Sponsored by the Academy of Molecular Imaging and managed by the American College of Radiology through the American College of Radiology Imaging Network, the NOPR is implementing this registry for CMS. Considering the impact of the NOPR, PET will surely continue to grow as the CMS begins to cover for more cancers the diagnosis, initial staging, treatment monitoring during therapy (chemotherapy, radiation therapy, or combined modality therapy) and re-staging after completion of therapy and detection of suspected recurrence.

A PET/CT scanner should not be expected to operate more weekly hours than other diagnostic modalities such as computed tomography (CT) or magnetic resonance imaging (MRI). Unlike CT or MRI that must operate 66 hours per week as per 10A NCAC 14C.2302(k) or 10A NCAC 14C.2702(c)(1), respectively, PET/CT scanners are being held to an operational standard of 72 hours per week per 10A NCAC 14C.3702(b)(3)(B). Perhaps this requirement is based upon the lengthy total exam time of approximately 2 to 2.5 hours for PET. For example, the uptake time of the ^{18}FDG is generally 60 to 90 minutes, followed by a scan that takes approximately 25 to 30 minutes. But, unlike CT and MRI that are used for innumerable indications, PET is used for a small subset of the general patient population that includes primarily oncology patients. Furthermore, unlike CT and MRI which may be staffed to operate 24 hours a day to meet urgent and emergent needs, the daily PET schedule is limited to the availability of the cyclotron-produced ^{18}FDG from regional vendors – at FMC, we are only able to offer access to PET services only 12 hours per day.

Oncology is only one specialty that utilizes PET. For example, cardiology patients may benefit from ^{18}FDG exams to assess myocardial viability and neurology patients may benefit from exams to diagnose Alzheimer's as Medicare does reimburse PET scans for these indications. But because FMC is committed to providing the best patient care in a timely manner, we have not yet fully introduced our PET services to the cardiologists or neurologists nor have we begun to implement therapy treatment planning with the radiation oncologists. Since the availability of FMC's one PET/CT scanner is limited to just 12 hours per day as described above, we look forward to the opportunity to seek the state's approval for a second PET/CT scanner in 2008. This will better enable us to provide excellent service to a wider variety of referring physicians whose patients would benefit from PET diagnostic studies.

Thank you for the opportunity to provide comments in support of the Health Service Area (HSA) II PET Scanner Need Determination in the Proposed 2008 State Medical Facilities Plan. If I may provide additional information, please contact me at (336) 718-5844.

Sincerely,

Vito Basile, M.D.

Vito Basile, M.D., Medical Director
Department of Radiology
Forsyth Medical Center

National Oncologic PET Registry (NOPR)

Cancers and Indications Eligible for Entry into NOPR

(Information available at http://www.cancerpetregistry.org/indications.htm)

Indications	Diagnosis	Staging	Restaging	Monitoring
Anus	√	√	√	√
Bladder	√	√	√	√
Bone/cartilage	√	√	√	√
Brain, Primary	√	√	√	√
Breast, female	NC	C1	C	C
Breast, male	√	√	√	√
Cervix	√	C2	√	√
Colon and Rectum	C	C	C	√
Connective/other tissue	√	√	√	√
Esophagus	C	C	C	√
Eye	√	√	√	√
Gallbladder and extrahepatic bile ducts	√	√	√	√
Kaposi's sarcoma	√	√	√	√
Kidney and other urinary tract	√	√	√	√
Larynx	C	C	C	√
Leukemia	√	√	√	√
Lip, Oral Cavity, and Pharynx	C	C	C	√
Liver and intrahepatic bile ducts	√	√	√	√
Lung, non-small cell	C	C	C	√
Lung, small cell	√	√	√	√
Lymphoma	C	C	C	√
Melanoma of skin	C	C1	C	√
Myeloma	√	√	√	√
Nasal cavity, ear, and sinuses	C	C	C	√
Ovary and uterine adnexa	√	√	√	√
Pancreas	√	√	√	√
Penis and other male genitalia	√	√	√	√
Pluera	√	√	√	√
Prostate	√	√	√	√
Retroperitoneum and peritoneum	√	√	√	√
Single Pulmonary Nodule	C	NA	NA	NA
Small Intestine	√	√	√	√
Stomach	√	√	√	√
Testis	√	√	√	√
Thymus, heart, mediastinum	√	√	√	√
Thyroid	√	√	C3	√
Uterus, body	√	√	√	√
Uterus, unspecified	√	√	√	√
Other or not listed	√	√	√	√

√ Eligible for entry in NOPR

C Not eligible for entry in NOPR (because already nationally covered indication)

NC Not eligible for entry in NOPR (because nationally non-covered indication)

NA Not applicable

1 Does not cover initial staging for axillary lymph nodes for breast cancer patients and regional lymph nodes for melanoma patients

2 Patient must have prior CT or MRI negative for extrapelvic metastatic disease to qualify as a covered indication. Patients who do not qualify for covered indication (e.g., because CT or MRI not done or because either showed extrapelvic metastatic disease) can be entered on NOPR.

3 To qualify as a covered indication thyroid cancer must be of follicular cell origin and been previously treated by thyroidectomy and radioiodine ablation and have a serum thyroglobulin > 10 ng/ml and negative I-131 whole body scan. Patients who do not qualify for covered indication (because tumor other than follicular cell origin or thyroglobulin not elevated) can be entered on NOPR.

Exhibit C

DUKE UNIVERSITY MEDICAL CENTER
R. Edward Coleman, M.D.
Professor and Vice Chairman
Department of Radiology

May 14, 2007

Mr. Tom Elkins, Planner
Medical Facilities Planning Section
Division of Facility Services
N. C. Department of Health & Human Services
701 Barbour Drive
Raleigh, NC 27603

Re: PET/CT Capacity

Dear Tom:

Duncan forwarded me your question about the feasibility of increasing the capacity of fixed dedicated PET scanners in the need methodology incorporated in the State Medical Facilities Plan.

For several reasons your inquiry is perfectly timed:

1. The PET/CT scanners now being purchased are significantly faster than the PET-only scanners that they have replaced. In short, we now have enough experience with the PET/CT to revise the need methodology to assume its use.

2. The technology has stabilized. The PET/CT we will install later this year is no faster or more efficient than the PET/CT we installed 4 years ago, and I do not foresee any significant change in the years ahead.

Our experience suggests that the capacity of a fixed dedicated PET/CT scanner is 15 procedures a day. During the year ended June 30, 2006 our PET/CT provided 3,327 procedures, for an average of 13.3 per day. With the demand continuing to increase, we have lengthened our schedule and our PET/CT now averages 15 procedures per day.

To maintain that volume, our staff arrives about 6:30 A.M. every weekday, the first patient is scheduled at 6:45 A.M., the last patient is scheduled at 5:00 P.M. but is usually scanned close to 6:00 P.M., and the service closes at 6:30 P.M.

DUMC 3949 • Durham, NC 27710 • Phone (919) 684-7244 • Fax (919) 684-7135 • E-mail: colem010@mc.duke.edu

If 15 per day were capacity, a fixed dedicated PET/CT scanner could provide 3,750 procedures per year (15 x 250). Given the length of time required to bring an additional machine on line, I would make the threshold a volume of 10 procedures per day or 2,500 per year. Even though new indications will not expand the use of PET scanning in the next few years, the demand is likely to continue increasing about 15% per year, and we in North Carolina should be positioned to meet that demand.

I hope that these suggestions are helpful. If you have questions or need further information, please let me know.

Sincerely,

R Edward Coleman

R. Edward Coleman, M.D.
Vice Chair, Department of Radiology
Professor of Radiology
Director of Nuclear Medicine

cc: Duncan Yaggy

Exhibit D

Proposed 2008 SMFP

Table 9K: PET Scanner Utilization of Existing Fixed Dedicated Scanners

Center	Procedures 2002-2003	2003-2004	2004-2005	2005-2006	HSA	Inventory	Utilization Rate Year 2006 Procedures / 2600 as Capacity	Need Determination by Criteria - 80% of Present Capacity
Mission Hospitals (f)		644	875	1003	I	1	38.58%	
Catawba Valley Frye Reg. (j)			848	1258	I	1	48.38%	
N.C. Baptist Hospitals	1817	1797	1266	1477	II	1	56.81%	
Moses Cone Health System (o)			1352	1760	II	1	67.69%	
Forsyth Medical Center (p)		130	1579	2417	II	1	92.96%	1
High Point Regional (r)		179	356	574	II	1	22.08%	
Alamance Reg. Medical Ctr. (u)				374	II	1	14.38%	mobile procedures
Carolinas Med Center(a),(k)	2414	2908	3049	3635	III	2	69.90%	
Gaston Mem. / CIS Summit (m)		172	700	846	III	1	32.54%	
NorthEast Medical Center (n)		330	481	615	III	1	23.65%	
The Presbyterian Hospital (q)			1544	1988	III	1	76.46%	
Iredell Memorial Hospital (t)				NA	III	1	NA	
Duke Univ. Hospital (d)	3259	3135	3091	3596	IV	2	69.15%	
UNC Hospitals (b)	1230	1389	1144	1386	IV	2	26.65%	
Rex Hospital (e)	407	1116	1544	1913	IV	1	73.58%	
Wake PET Services, Wake Radiology Oncology, Wake Radiology, WakeMed (s)				NA	IV	1		
New Hanover Reg. Med. (g)			582	755	V	1	29.04%	
Cape Fear Valley Medical Ctr. (h)		629	1218	2069	V	1	79.58%	0
First Imaging of the Carolinas (i)		351	529	550	V	1	21.15%	
Pitt Co. Memorial (c)		418	393	832	VI	1	32.00%	
Craven Reg. Medical (l)			719	831	VI	1	31.96%	
Nash General Hospital (u)				336	VI	1	12.92%	mobile procedures
TOTAL	9,127	13,198	21,270	28,215		25		1

t9k2008p xls (6/18/2007)

NA Not Applicable for time period ending September 30, 2006.

(a) Approved for additional scanner in November 2001.
(b) Approved for scanner in June 2000 and additional scanner under Policy AC-3 in November 2005.
(c) Approved for scanner in August 2001.
(d) Approved for additional scanner under Policy AC-3 in September 2002.
(e) Approved for scanner in September 2002.
(f) Approved for scanner in January 2003.
(g) Operational in October 2004.
(h) Approved for scanner in August 2003.
(i) Approved for scanner in August 2003.
(j) Approved for scanner in July 2003.
(k) Approved for replacement of 1 scanner in June 2003
(l) Approved for scanner in October 2003.
(m) Approved for scanner in December 2003.
(n) Approved for scanner in December 2003.
(o) Operational in October 2004.
(p) Approved for scanner in June 2004.
(q) Approved for scanner in June 2004.
(r) Approved for scanner in January 2005.
(s) Approved for scanner in November 2005.
(t) Approved for scanner in January 2007.
(u) Approved for scanner in April 2007.
(v) Approved for scanner in May 2007

EXHIBIT D

Table 9G: Hospital and Free-Standing Linear Accelerators and Radiation Oncology Procedures (see note at bottom of table)

Facility Name	Service Area #	County	LIN ACC	PROCEDURES (FSTVs) 2005-2006	Average per Unit
Harris Regional Hospital, Inc.-Mtn Trace	1	Jackson	1	4,503	4,503
NC Radiation Therapy - Franklin	1	Macon	1	2,277	2,277
Mission Hospitals (S) (b)	2	Buncombe	3	20,766	6,922
NC Radiation Therapy - Asheville	2	Buncombe	2	7,012	3,506
NC Radiation Therapy - Clyde	2	Haywood	1	4,359	4,359
NC Radiation Therapy - Marion	2	McDowell	1	2,534	2,534
Watauga Hospital	3	Watauga	1	4,491	4,491
Margaret Pardee Mem. Hospital	4	Henderson	1	6,591	6,591
NC Radiation Therapy - Brevard	4	Transylvania	1	1,709	1,709
NC Rad.Therapy - Hendersonville	4	Henderson	1	645	645
Catawba Valley Medical Center	5	Catawba	2	18,008	9,004
Frye Regional Medical Center	5	Catawba	1	NA	NA
Grace Hospital, Inc.	5	Burke	1	NR	NR
Valdese General	5	Burke	1	6,082	6,082
Caldwell Memorial Hospital, Inc.	5	Caldwell	1	1,056	1,056
Cleveland Regional	6	Cleveland	1	6,989	6,989
Gaston Memorial Hospital (h)	6	Gaston	3	11,761	3,920
NC Radiation Therapy - Forest City	6	Rutherford	1	4,656	4,656
2006 SMFP Need Determination	7		1		
Carolinas Medical Center (S)	7	Mecklenburg	3	14,128	4,709
CMC-Union Reg. Medical Center (i)	7	Union	1	8,428	8,428
Matthews Radiation Oncology	7	Mecklenburg	1	10,803	10,803
Presbyterian Hospital	7	Mecklenburg	4	16,659	4,165
University Radiation Oncology	7	Mecklenburg	1	7,289	7,289
Iredell Memorial	8	Iredell	2	6,834	3,417
Lake Norman Radiation Oncology Ct	8	Iredell	1	4,641	5,525
Rowan Regional Medical Center	8	Rowan	1	5,519	5,519
NorthEast Medical Center	9	Cabarrus	2	13,009	6,505
Stanly Regional Medical Center	9	Stanly	1	4,427	4,427
Forsyth Memorial Hospital	10	Forsyth	4	28,435	7,109
Hugh Chatham Memorial Hospital (d)	10	Surry	1	3,911	3,911
N. C. Baptist Hospitals (S)	10	Forsyth	4	20,251	5,063
2006 SMFP Need Determination	11	Davidson	1		
High Point Regional Health System	12	Guilford	2	9,344	4,672
Morehead Memorial Hospital	12	Rockingham	1	5,972	5,972
Moses Cone Health System	12	Guilford	4	28,362	7,091
Randolph Cancer Center (m)	13	Randolph	1	NA	NA
UNC Hospitals (S)	14	Orange	4	22,224	5,556

EXHIBIT D

Table 9G: Hospital and Free-Standing Linear Accelerators and Radiation Oncology Procedures (see note at bottom of table)

Facility Name	Service Area #	County	LIN ACC	PROCEDURES (ESTVs) 2005-2006	Average per Unit
Alamance Regional Medical Center (j)	15	Alamance	2	7,991	3,996
Duke University Hospital (S)	16	Durham	5	36,634	7,327
Durham Regional Hospital	16	Durham	1	6,128	6,128
Maria Parham Hospital (e)	16	Vance	1	4,833	4,833
FirstHealth Moore Regional	17	Moore	2	23,764	11,882
Scotland Memorial Hospital (1)	17	Scotland	1	4,122	4,122
Cape Fear Valley Medical Center (a)	18	Cumberland	4	27,631	6,908
Southeastern Regional Medical Center	18	Robeson	1	9,484	9,484
New Hanover Radiation Oncology	19	New Hanover	2	15,156	7,578
New Hanover Regional Med Ctr	19	New Hanover	1	7,599	7,599
South Atlantic Radiation Oncology, LLC (c)	19	Brunswick	1	NA	0
2007 SMFP Need Determination	20		1		
Cancer Ctrs of NC - Raleigh Hematology	20	Wake	1	8,924	8,924
Duke Raleigh Hospital	20	Wake	1	7,323	7,323
Rex Hospital	20	Wake	4	16,184	4,046
Wake Radiology Oncology Services	20	Wake	1	5,960	5,960
Triangle Radiation Oncology Services	21	Johnston	1	2,648	1,093
2006 SMFP Need Determination	21	Johnston	1		
Lenoir Memorial	22	Lenoir	1	6,147	6,147
Wayne Radiation Oncology Center	22	Wayne	1	6,952	6,952
Carteret General (g)	23	Carteret	1	4,015	4,015
Craven Regional Med Ctr	23	Craven	2	12,415	6,208
2006 SMFP Need Determination	24	Onslow	1		
Nash Day Hospital	25	Nash	2	7,905	3,953
Roanoke Valley Cancer Center	25	Halifax	1	3,208	3,208
Wilson Memorial Hospital	25	Wilson	1	4,413	4,413
Ahoskie Cancer Center	26	Hertford	1	3,173	3,173
Carolina Radiation Medicine, P.A. (f) (S)	26	Pitt	1	8,206	8,206
Pitt County Memorial Hospital (S)	26	Pitt	3	16,013	5,338
Albemarle Hospital	27	Pasquotank	1	4,403	4,403
Outer Banks Cancer Center	27	Dare	1	4,977	4,977
TOTALS (64 Facilities)			**112**	**579,883**	**5,178**

1
5
4

Note: The above inventory of linear accelerators is subject to change if it is determined that any of the listed equipment was not acquired in accordance with N.C. G. S. 131E-175, et.seq, prior to August 26, 2005.

T9G2008p.xls (06/6/2007)

Source: NOPR WebSite

EXHIBIT E

Cancers and indications that are reimbursable by Medicare are NOT eligible for entry in the NOPR. Cancers and indications that are specifically excluded for Medicare reimbursement are also not eligible for entry in the NOPR.

IMPORTANT NOTE: The scientific evidence concerning the clinical utility of FDG-PET is generally less robust for cancers and indications that are currently covered by Medicare only in the NOPR than for cancers and indications that are currently covered without clinical data submission to the NOPR. For this reason, Medicare has conditioned coverage of FDG-PET under the NOPR on the collection of clinical data. These data will be used to help determine the clinical utility of FDG-PET for conditionally covered cancers and indications. The billing physician remains responsible for documenting medical necessity, which is required for the coding and billing of both covered and NOPR-eligible PET studies. Eligibility for the NOPR does not constitute a clinical management recommendation for the use of PET for the conditionally covered cancers and indications, by either the Medicare program or NOPR investigators. Referring and interpreting physicians are thus advised to refer to the published literature to better understand the potential limitations of FDG-PET for NOPR-eligible uses.

CANCERS AND INDICATIONS ELIGIBLE FOR ENTRY IN THE NOPR

✓ = Eligible for Entry in NOPR

C = Not Eligible for Entry in NOPR - nationally covered indication.

NC = Not Eligible for Entry in NOPR - nationally non-covered indication.

NA = Not Applicable

Indications	Diagnosis	Initial Staging	Treatment Monitoring	Restaging/Suspected Recurrence
Lip, Oral Cavity, and Pharynx (140-149)	C	C	✓	C
Esophagus (150)	C	C	✓	C
Stomach (151)	✓	✓	✓	✓
Small Intestine (152)	✓	✓	✓	✓
Colon (153) and Rectum (154)	C	C	✓	C
Anus (154)	✓	✓	✓	✓
Liver and intrahepatic bile ducts (155)	✓	✓	✓	✓

Gallbladder & extrahepatic bile ducts (156)	✓	✓	✓	✓
Pancreas (157)	✓	✓	✓	✓
Retroperitoneum and peritoneum (158)	✓	✓	✓	✓
Nasal cavity, ear, and sinuses (160)	C	C	✓	C
Larynx (161)	C	C	✓	C
Lung, non-small cell (162)	C	C	✓	C
Lung, small cell (162)	✓	✓	✓	✓
Pleura (163)	✓	✓	✓	✓
Thymus, heart, mediastinum (164)	✓	✓	✓	✓
Bone/cartilage (170)	✓	✓	✓	✓
Connective/other soft tissue (171)	✓	✓	✓	✓
Melanoma of skin (172)	C	C[2]	✓	C
Female breast (174)	NC[3]	C[2]	C	C
Male breast (175)	NC[3]	C[2]	C	C
Kaposi's sarcoma (176)	✓	✓	✓	✓
Uterus, unspecified (179)	✓	✓	✓	✓
Cervix (180)	✓	C[4]	✓	✓
Uterus, body (182)	✓	✓	✓	✓
Ovary and uterine adnexa (183)	✓	✓	✓	✓
Prostate (185)	✓	✓	✓	✓
Testis (186)	✓	✓	✓	✓

Penis and other male genitalia (187)	✓	✓	✓	✓
Bladder (188)	✓	✓	✓	✓
Kidney and other urinary tract (189)	✓	✓	✓	✓
Eye (190)	✓	✓	✓	✓
Primary Brain (191)	✓	✓	✓	✓
Thyroid (193)	✓	✓	✓	C[5]
Lymphoma (200-202)	C	C	✓	C
Myeloma (203)	✓	✓	✓	✓
Leukemia (204-208)	✓	✓	✓	✓
Solitary Pulmonary Nodule	C	NA	NA	NA
Other or not listed	✓	✓	✓	✓

NOTES:

1. Some Medicare carriers include anal cancer in their coverage of "colorectal cancer"; for PET facilities served by those carriers, PET for anal cancer diagnosis, initial staging, or restaging/suspected recurrence would be a covered indication.
2. Does not cover initial staging for axillary lymph nodes for breast cancer patients and regional lymph nodes for melanoma patients
3. PET is non-covered for "Diagnosis" of breast cancer to evaluate a suspicious breast mass. However, a patient with suspected breast cancer is eligible for entry in NOPR for the indications (1) "Diagnosis: Unknown Primary Site" in a patient with axillary nodal metastasis but no evident primary breast cancer by conventional evaluation and (2) "Diagnosis: Paraneoplastic Syndrome".
4. Patient must have prior CT or MRI negative for extrapelvic metastatic disease to qualify as a covered indication. Patients who do not qualify for covered indication (e.g., because CT or MRI not done or because either showed extrapelvic metastatic disease) can be entered on NOPR.
5. To qualify as a covered indication thyroid cancer must be of follicular cell origin and been previously treated by thyroidectomy and radioiodine ablation and have a serum thyroglobulin > 10ng/ml and negative I-131 whole body scan. Patients who do not qualify for covered indication (e.g., because tumor of other than follicular cell origin or thryoglobulin not elevated) can be entered on NOPR.

GENERAL NOTE:

PET imaging of the brain with CPT code 78608 for diagnosis, initial staging, treatment monitoring, or restaging/suspected recurrence of any type of

cancer is covered only under NOPR.

NOPR

NATIONAL ONCOLOGIC PET REGISTRY

Home

What is The NOPR ▼

Participating Organizations

[illegible]

[illegible]

Operations Manual

NOPR Forms ▼

Info For PET Facilities ▼

Info For Referring ▼ Physicians

Info For Patients

PET Facility Registration

Registered Users

Frequently Asked Questions

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Monthly Status Report

Contact Us

What is the NOPR

NOPR Background
The National Oncologic PET Registry (NOPR) was developed in response to the Centers Services proposal to expand coverage for positron emission tomography with F-18 fluo include cancers and indications not presently eligible for Medicare reimbursement. Mec these cancers can now be obtained if the patient's referring physician and the provider registry to assess the impact of PET on cancer patient management. The NOPR is impl CMS. The NOPR is sponsored by the Academy of Molecular Imaging and managed by the through the American College of Radiology Imaging Network.

The NOPR received input from, and is endorsed by the ACR, the American Society for C Society for Nuclear Medicine.

NOPR Status Update
The NOPR began accepting facility registrations in late November 2005 and patient reg 2006.

How to Register as a Participating Site
Any PET facility that is approved to bill CMS for either technical or global charges can NOPR. Sites are not required to have ACR or ICANL accreditation to participate. Intere via the Facility Registration tool on the NOPR Web site, www.CancerPETregistry.org. The fa Facility Pre-Registration and Registration Forms online through the PET Facility Registrat Registration process the facility must send an executed ACR HIPAA Business Associate A Headquarters at 1818 Market Street, Philadelphia, PA 19103. The ACR HIPAA BAA is a site under Sample Forms. NOPR will assign a facility ID number and send an invoice fo ($50) and the escrow account (amount determined by the facility).

How to Register as a Participating Site
Any PET facility that is approved to bill CMS for either technical or global charges can NOPR. Sites are not required to have ACR or ICANL accreditation to participate. Intere via the Facility Registration tool on the NOPR Web site, www.CancerPETregistry.org. The fa Facility Pre-Registration and Registration Forms online through the PET Facility Registrat the Registration process the facility must send an executed ACR HIPAA Business Associate A Headquarters at 1818 Market Street, Philadelphia, PA 19103. The ACR HIPAA BAA is a site under Sample Forms. NOPR will assign a facility ID number and send an invoice fo ($50) and the escrow account (amount determined by the facility).

Patient Eligibility
Medicare beneficiaries who are referred for PET for essentially all oncologic indications reimbursable under Medicare are eligible to participate in the NOPR. The [illegible] indications that will be accepted in the Registry.

PET Facility Responsibilities
The PET facility is responsible for collecting and entering patient data into the Registry application at www.CancerPETregistry.org. Below is a brief summary of the data collec

- When a patient eligible for entry into the NOPR presents at the PET facility, the referring physician and obtains confirmation that the referring physician will su data requirements.
- The facility registers the patient on the NOPR via a Web form, at which time a I assigned.
- The NOPR will e-mail confirmation to the PET facility and at the same time e-m form to the PET facility for delivery to the referring physician.

- The referring physician must complete and return the Pre-PET Form to the PET f must enter the Pre-PET Form into the NOPR database by midnight of the day o
- At some time before the PET study, or when the patient arrives for the PET sca provide the patient with the ACR IRB-approved standard NOPR Patient Informa the NOPR Web site. The patient will be able to contact the NOPR directly for mc The patient will indicate his or her consent verbally to staff at the PET facility, e study or within two working days after the PET study is completed. Written con PET facility will note in the database and on the PET Report Form, if the patient for use of his or her data in future NOPR research.
- After the PET scan is performed, the PET facility sends the PET report to the rel study completion date into a Web form, and submits the report text electronica Note that the PET scan must be completed and the PET Scan Completion Form database within 14 days of case registration or the case will be marked as ineli
- After the PET Scan Report Form is entered, the database will send the PET facil PET Form for delivery to the referring physician. This form will also include an A Physician Information Sheet. The physician will indicate on the Post-PET Form v the response data in future NOPR research has been given or withheld. All data dataset used by NOPR investigators for research will contain only the data of p both have consented to have the data included. This form must be completed, and entered into the NOPR database within 30 days of the PET scan.

Referring Physician's Responsibilities
The patient's referring physician must agree to complete pre- and post-PET data collec approximately 5 questions regarding the patient's planned management.

- The Pre-PET Form must be completed by the referring physician and returned t patient's PET scan. A blank Pre-PET Form can be downloaded from the NOPR We facility at the time of patient referral. If the form is not submitted with the refe will be e-mailed to the PET facility for delivery to the referring physician. The P to the PET facility via, FAX, mail, or hand delivery.
- After the PET is performed a patient-specific Post-PET Form will be e-mailed to tl the referring physician for completion within 30 days. This form will also includ Referring Physician Information Sheet. The physician will indicate on the Post-F for use of the response data in future NOPR research has been given or withhe CMS, but the dataset used by NOPR investigators for research will contain only physicians when both have consented to have the data included. This form can facility via FAX, mail, or hand delivery.

The case is eligible for CMS reimbursement only if the Pre-PET Form is completed and prior to the PET scan and the Post-PET Form is completed and returned within 30 days

How to Obtain Medicare Reimbursement
The NOPR database will notify the PET facility when all case data have been entered. T CMS for the study. The PET facility can check on the case status of their patients at an tools available on the NOPR Web site.

Sponsored by:

- Academy of Molecular Imaging

Endorsed by:

- American College of Radiology
- American Society of Clinical Oncology
- Society for Nuclear Medicine

Managed by:

- American College of Radiology
- American College of Radiology Imaging Network

Advisor:

- Centers for Medicare & Medicaid Services

NOPR Working Group

- **Chair:**
  - *Bruce Hillner, M.D.,*
    Virginia Commonwealth Univ.,
    (804) 828-5129
    [redacted]
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  - *Barry Siegel, M.D.,*
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  - *R. Edward Coleman, M.D.,*
    Duke University,
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  - *Anthony Shields, M.D.,*
    Wayne State University,
    (313) 576-8735
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Proposed 2008 State Medical Facilities Plan
Public Hearing – August 1, 2007

Public Hearing Comments on Behalf of Forsyth Medical Center
Wallace C. Hollowell, III

- Good afternoon. My name is Chuck Hollowell. I am an attorney with the law firm Nelson Mullins Riley & Scarborough, LLP. I am speaking today on behalf of Forsyth Medical Center.
- Forsyth Medical Center submitted a comment on the Proposed 2008 State Medical Facilities Plan ("SMFP") at the July 20, 2007 public hearing.
- Today's remarks are made in support of this comment by Forsyth Medical Center.

- The Proposed 2008 SMFP currently shows a need for one additional fixed PET scanner in HSA II, where Forsyth Medical Center is located.
- This need determination is based on a methodology that sets capacity for a fixed PET scanner at 2,600 procedures per year. A need for an additional PET scanner is recognized when an existing fixed PET scanner is utilized at or above 80% of this capacity – or 2,080 procedures per year.
- The need set forth in the Proposed 2008 SMFP was generated as a result of Forsyth Medical Center's utilization of its existing PET scanner, which was at approximately 93% of capacity.

- There is some concern that there may be an attempt to change the methodology for projecting the need for fixed PET scanners at this late date in the development of the 2008 SMFP.
- As far as Forsyth Medical Center is aware, no formal petition has been submitted to the SHCC to make such a change.
- Instead, Dr. Edward Coleman from Duke University Medical Center submitted a letter in May to Mr. Elkins in the Planning Section suggesting that the need for an additional PET scanner should be recognized when an existing fixed PET scanner is performing 2,500 procedures per year – as opposed to 2,080 procedures as set forth in the Proposed 2008 SMFP.
- Based on this letter, there was discussion at the May 16 meeting of the SHCC's Technology and Equipment Committee that this threshold should be raised.
- Subsequently, a "PET Scanner Discussion Group Meeting" has been scheduled for August 15, 2007.
- Forsyth Medical Center is concerned that there may be an attempt to change the need methodology for PET scanners after the public hearing process for the Proposed 2008 SMFP has ended.
- Forsyth Medical Center believes this would be improper.

- The 2007 SMFP sets forth very clear procedures governing petitions to change the SMFP's need methodologies. The 2007 SMFP states that any petitions proposing a

revision to the need methodologies must be submitted to the Planning staff as early in the year as possible, and no later than March 7, 2007. It states that these types of changes will need to be considered in the first four months of the calendar year as the Proposed SMFP is being developed.

- Thus, the 2007 SMFP makes it very clear that any proposal to change a need methodology in the SMFP, must be submitted early in the year, so that it can be considered during the first four months of the year. This allows such fundamental changes to be fully considered by the SHCC and incorporated into the Proposed SMFP, which is then made available for review and comment in a timely manner. This allows such fundamental changes to be considered as part of the public hearing process that is taking place at this time.
- In the notice from the Department of Health and Human Services regarding the public hearing process, it states: "The hearings provide the public an opportunity to comment on all aspects of the proposed plan."
- Mr. Fitzgerald is quoted as saying: "Public comment is a critical part of the process that shapes and fine-tunes the State Plan."
- If such a fundamental change in a need methodology is not proposed or considered until *after* the public hearing process has ended, then this deprives the public of the opportunity to comment on such changes.
- It would be directly contrary with the procedures governing the development of the annual SMFP to first consider a proposal affecting a need methodology at an August 15 "PET Discussion Group Meeting" that takes place *after* the final public hearing on August 1.
- Such a change can only be properly considered as part of the preparation of the 2009 SMFP next year.

- If the need methodology for PET is changed at this time, this would likely eliminate the need determination in the 2008 SMFP for an additional fixed PET scanner in HSA II.
- However, there are numerous reasons why this would not be appropriate.
- These issues are discussed in detail in the written comments that Forsyth Medical Center previously submitted regarding this issue at the July 20 public hearing in Greensboro.
- To highlight just a few of these reasons:

    - Table 9K in the Proposed 2008 SMFP shows that Forsyth Medical Center ranks *first* out of 22 facilities in the State with PET scanners in terms of PET scanner utilization, with utilization at approximately 93% of capacity;
    - The Proposed 2008 SMFP recognizes that "the clinical use of PET scanning is increasing rapidly, and the new applications involve the diagnosis of cancer;"
    - It appears likely that other PET codes will be added for reimbursement, such as those for cancer treatment monitoring and re-staging of cancer recurrence; and
    - Table 9G in the Proposed 2008 SMFP shows that Forsyth Medical Center ranks *second* out of 64 facilities in the State providing radiation oncology service in the number of procedures performed.

- Thus, Forsyth Medical Center currently has the highest utilization of its existing PET scanner of any scanner in the State, and this utilization is only expected to increase given the Forsyth Medical Center's robust cancer treatment program and the increasing number of cancer-related PET applications

- For these reasons, as well as those set forth in the materials previously submitted by Forsyth Medical Center, we respectfully request that the SHCC not take any action to change the need methodology for PET at this late date in the development of the 2008 SMFP.
- Any such changes should only be made pursuant to the clear process set forth in the SMFP, which allows for all of these issues to be fully considered during the development of the Proposed SMFP, including as part of the public hearing process.
- Thank you.

DFS Health Planning
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Medical Facilities
Planning Section

Forsyth MEDICAL CENTER

Draft SMFP 08 Public Hearing
Friday, July 20, 2007
Greensboro, NC
PET Comment by Forsyth Medical Center

Summary of Speaker Remarks in Support of the FMC PET Comment In Support of the Need for One New PET Scanner in HSA II in the Proposed 08 State Medical Facilities Plan

Comments from Vito Basile, M.D.
Medical Director of Radiology
Forsyth Medical Center, Winston-Salem, NC
And
Board-Certified Radiologist, Forsyth Radiological Associates

- Talked about his previous PET experience at an academic institution, when he was in training at the Cleveland Clinic and PET diagnostics were just in the research stage and not in very widespread use outside the academic setting
- Today, as a body imager who specializes in CT, he really appreciates the value-added diagnostic capabilities that PET offers, beyond what CT diagnostics can provide
- The utility of PET has allowed us to really change the way patients are managed; Dr. Basile has seen this firsthand from his active participation with the Forsyth Regional Cancer Center's regular Tumor Board Conferences where experts in surgery, radiation therapy, pulmonology, hematology/oncology, etc. incorporate PET diagnostic information into diagnosis and treatment planning for cancer patients; the PET diagnostic information is have a beneficial impact on the management of the care and treatment of these patients
- Many of our current PET scanner patients are cancer patients, who are often fragile and in a compromised state of health. Thus, late evening PET diagnostic appointments are not always optimal for them or their caregivers or transportation providers
- Dr. Basile is confident that the PET technology and diagnostics are here to stay and will prove themselves useful in the diagnosis and treatment of many other disease processes and illnesses involving neurology, cardiac, orthopedics, infectious disease
- FMC has not yet begun to utilize the scanner for its widest referral base – our current patient load is primarily for oncology and does not yet include cardiology or neurology patients.

Comments from Carmine Plott, Ph.D., CHP
Radiation Safety Officer
Forsyth Medical Center, Winston-Salem, NC

- My first job after graduate school was at the University of Tennessee Medical Center at Knoxville and we advertised ourselves as the first clinical PET site in the country. Up to that point, all PET centers were purely research-oriented. I'm proud that I have worked in PET for 20 years and have seen it expand from a research modality to a clinically viable modality that is now the standard of care for oncology patients.
- I don't understand the requirement for PET centers to operate 72 hours per week while CT and MRI operate only 66 hours per week. Perhaps this is due to the time required for a PET

exam which is about 2-1/2 hours. After the patient is injected with the radiopharmaceutical, the patient waits 60 to 90 minutes for the radioactivity to circulate throughout the body. The scan follows and takes up to 30 minutes.

- We rely on a regional radiopharmacy to provide us the FDG. Fluorine-18 is used to make FDG and the half-life is only 110 minutes. We are required to work more hours in PET (than CT or MRI), yet we utilize a material with a very short half-life that is cyclotron produced. It is easer to get doses during normal working hours (8 AM to 5 PM) than it is to get doses late in the day (5 PM to 11 PM). Although the vendor is accommodating, we don't have a limitless supply of FDG.
- We have a good working relationship with the regional FDG vendor and we are confident that they would work with us to increase the amount of FDG provided if FMC were to get a second PET scanner; this vendor already works well with us to get early evening doses of FDG for our PET scans that occur after 5 p.m.
- The current hours of operation for the FMC PET/CT scanner are 6:30 a.m. to 11:00 p.m., Monday – Friday (or over 75 hours per week)

Comments from Mr. Devi Mecum, RT(R)(CV)
Radiology Clinical Manager
Forsyth Medical Center, Winton-Salem, NC

- As a manager, I serve several customers: the radiologist, the referring physician, and most importantly, the patient. I must also comply with all applicable regulations to ensure the safety of the patient and the employee.
- It is my job to: (a) ensure that the diagnostic images are excellent; (b) to communicate the diagnostic PET information to the FMC Cancer Center as efficiently and effectively as possible; (c) to ensure the safety of the patients and the staff that handle and come in contact with the radioactive radiopharmaceutical that is part of the PET diagnostic study; (d) to help manage capacity, throughput, and access to the PET scanner; and (e) to be certain that PET diagnostics are available to referring physicians who care for cancer patients as well as other referring physicians
- Because of demand, I must exercise "creative scheduling" to accommodate up to 18 patients per day on the single FMC PET/CT scanner.
- The indications for which Medicare (and thus other payors) will reimburse PET scans is continuing to expand and I believe this trend will continue based on the work of the National Oncologic PET Registry (NOPR)
- Private insurance providers generally follow Medicare with regard to PET reimbursement. CMS currently reimburses for only 9 cancers. But the National Oncologic PET Registry is a prime example of Medicare's interest in PET. Once Registry data are collected and analyzed, CMS will likely expand its list to include even more indications – so I expected that the PET/CT scanner at FMC will be flooded with even more requests for PET diagnostic studies.
- We need a second scanner to accommodate the needs of our patients, their referring physicians, and the families.

Comments from Sharon Murphy, Executive Director
Derrick L. Davis Forsyth Regional Cancer Center
Forsyth Medical Center, Winston-Salem, NC

- Our cancer center at FMC has served, according to the NC Cancer Registry, over 3,000 newly diagnosed cancer patients in recent years
- The group of cancer physician experts associated with our cancer center includes: 11 medical-oncologists, 5 radiation oncologists, 4 gyn oncologists, and 20 _____
- The medical oncologists offer local access to cancer care in satellite offices located in towns of Winston-Salem, Kernersville, Lexington, Mt Airy, Statesville, Elkin, and Wilkesboro located in five Triad Region counties (Forsyth, Davidson, Iredell, Surry, and Wilkes)
- The patient base that we care for at the Forsyth Regional Cancer Center continues to grow and PET diagnostic information is now incorporated as part of our standard of care
- The PET Diagnostic information is part of the case presentations at our multi-disciplinary Tumor Board presentations; PET diagnostic information helps us plan for the most effective treatment and increases survivability
- To accommodate this growth our Cancer Center and the adjacent Hematologist-Oncologist Medical Office building is now under expansion, which will add 10-15,000 SF of treatment and support space to better serve our patients, families, and physicians

File: PETForsythComments08SMFPPublicHrGboroBasilePlottMecumMurphy 07 20 07.doc

Top of Document

Technology and Equipment Committee Meeting

August 29, 2007

MRI Material

Top of Document

Technology and Equipment Committee Meeting

August 29, 2007

MRI Material

Material Related To

MRI Petition-1: Alliance Imaging

PETITION

TO: Medical Facilities Planning Section
Division of Facility Services
701 Barbour Drive
2714 Mail Service Center
Raleigh, NC 27699-2714

PETITIONER: Shirley Silva
Alliance Imaging Inc.
2428 Belle Terre Drive
Statesville, NC 28625-4331

DATE: July 24, 2007

RE: Petition for Adjusted Need Determination Related to Mobile MRI Scanners

I. Introduction

Earlier in 2007, Alliance Imaging petitioned for a change in Chapter 9 of the Proposed 2008 State Medical Facilities Plan to include the following statement:

"There is no need for any additional mobile magnetic resonance imaging scanners anywhere in the State."

The State Health Coordinating Council denied the earlier petition based on two factors:

- There may still be places where an applicant can demonstrate a need for mobile MRI to improve patient access
- Mobile PET and mobile cardiac catheterization units are more specialized and expensive as compared to mobile MRI. Therefore, it is appropriate for the Plan to state that no need exists for additional mobile PET and mobile cardiac catheterization units but not make a similar statement regarding mobile MRI.

Alliance Imaging respectfully requests that the State Health Coordinating Council reconsider this petition based on updated MRI utilization and mobile MRI inventory data.

II. Rationale for the Proposed Changes

Alliance Imaging offers the following updated information regarding the fixed and mobile MRI inventory and projected future needs for MRI procedures:

A. Growth in MRI Demand Has Leveled Off

The Proposed 2008 Plan shows that 785,445 total MRI procedures were performed in 2005-06 which represents a 65,998 or 9 percent increase over the previous year. The 2007 Plan shows that the previous reporting period 2004-05 had an increase of 65,548 procedures (or approximately 10 percent) over the previous year. These statistics show that growth in MRI demand has leveled off. The following table shows the volumes, inventory and need determinations for the proposed Plan and the previous two years.

	Volumes and Inventory		Need Determinations					
	Annual Volume Previous Yr	Fixed Equiv Total	Standard Fixed MRI	Breast MRI	Extremity MRI	Multi-Position MRI	Other MRI	Total MRIs
2008 Proposed	785,445	251 75	11	0	0	4	0	15
2007 Plan	719,447	237 36	7	0	0	0	0	7
2006 Plan	653,899	222 49	6	1	1	0	0	8

The 2008 Proposed Plan includes 11 need determinations for fixed MRIs based on the standard methodology plus an adjusted need determination for 4 multi-position MRI scanners. The total number of MRI need determinations is substantially larger than the two previous years'. The maximum capacity of these additional 15 scanners is calculated as follows:

15 MRI units x 6,864 MRI procedures = 102,960 procedures annual capacity
(The 6,864 annual procedures is based on the MRI methodology assuming 100 percent utilization.)

The MRI capacity that is being added in 2008 totals 102,960 and far exceeds the actual annual growth of approximately 66,000 MRI procedures that has occurred for each of the two previous years. This means that the proposed additional MRI scanners will probably take volume away from existing mobile units in specific markets.

B. Multi-Position MRI Scanners Can Not Be Installed in Mobile Units

Alliance Imaging has researched multi-position MRI scanners as described by Axiom and confirmed that these machines can not be installed in a mobile unit. Therefore mobile MRI scanners are not a legitimate settlement option to resolve any CON appeals for competitive reviews of multi-position MRI units.

C. The Actual Number of Currently Underutilized Mobile MRI Scanners Should Be Examined

The higher cost and complexity of mobile PET and mobile cardiac catheterization units are certainly legitimate reasons to make the statement in the Plan that no need exists for these units. In total there are far fewer of these types of units as compared to mobile MRI scanners.

The Medical Facilities Planning Section has the data available to determine the number of mobile MRI scanners that were underutilized during the previous year. This information is directly relevant to cost effectiveness and would be helpful to evaluate all mobile technologies.

D. Multiple Approved Mobile MRI Scanners Have Not Been Implemented

CON-approved mobile MRI scanners that are pending implementation include:

Frye Memorial Hospital was approved for a mobile unit on July 15, 2005 (# E-7059-04). No volumes have been reported for this scanner and no progress reports have been received by the CON Section

Alamance Regional Medical Center was CON approved for a mobile unit in November, 2004. Based on the 2007 Mobile MRI Inventory forms this scanner has not been implemented.

Waccamaw Ultrasound & Diagnostic, Inc. d/b/a Waccamaw Imaging (Columbus County) was issued a CON for a mobile MRI scanner effective November 27, 2006; no 2007 mobile MRI inventory form was submitted.

Raleigh Orthopaedic Clinic (Wake County) and Orthopaedic Specialists of the Carolinas (Forsyth County) both obtained CON approval in 2007 to acquire mobile MRI scanners. These units are not yet operational.

The MRI methodology (Table 9O) estimated "fixed equivalent MRI units" that are assigned to the above mobile MRI scanners; these numbers are only estimates of their future capacity based on the number of days per week assigned to the prospective host sites. Since the "fixed equivalent MRI units" data is speculative, as more mobile MRI scanners become CON approved but not operational, the MRI methodology becomes more unreliable.

III. Requested Changes

Alliance Imaging petitions for a change in Chapter 9 of the 2008 State Medical Facilities Plan to include the following statement:

"There is no need for any additional mobile magnetic resonance imaging scanners anywhere in the State."

The requested change is based on the updated utilization and inventory data combined with the abundance of fixed MRI need determinations plus the special need determinations for multi-position MRI scanners.

IV. Adverse Effects if the Changes Are Not Made

The following adverse effects are predicted if the proposed change is not adopted:

- Utilization of the existing mobile MRI scanners statewide will be compromised by the added capacity of recently approved mobile MRI units, plus the abundance of fixed MRI need determinations. Unnecessary duplication of services will result.
- The calculations of "MRI fixed equivalent magnets" will be distorted with even more mobile MRI scanners in the pipeline.
- Mobile MRI sites will be reshuffled, meaning legal challenges will likely occur related to declaratory rulings to add or change those host sites.
- CON applicants in competitive reviews and subsequent appeals may continue to seek mobile MRI units through settlement agreements.

V. Alternatives That Were Considered But Are Not Feasible

Two alternatives that were considered are outlined:

Developing a specific need methodology for mobile MRI scanners is not a feasible alternative because this strategy was previously pursued by Alliance Imaging in the development of the 2003 State Medical Facilities Plan. The previously proposed mobile MRI methodology demonstrated the need for additional mobile MRI scanners and the 2003 SMFP included need determinations for two additional mobile MRI scanners. However, the need methodology that was used to calculate this need was not adopted in the 2003 Plan. Therefore, Alliance Imaging concludes that the Medical Facilities Planning Section is not receptive to a specific need methodology for mobile MRI scanners.

Alliance considered petitioning for an adjusted need determination for only one additional mobile MRI scanner that would be deployed to provide service to new sites in any counties that currently have no mobile MRI host sites or fixed MRI scanners. This scenario could potentially create the opportunity for providers to put forth their best efforts to expand service to rural underserved populations. However, Alliance observed that most of the counties that lack mobile MRI host sites do not have sufficient referring physicians to maintain even one day per week service. Also, the mobile MRI inventory data shows multiple providers with underutilized mobile scanners throughout the state. Therefore no need exists for even one additional mobile MRI scanner at this time.

VI. Evidence That the Proposed Change Will Not Result in Unnecessary Duplication of Health Resources

The proposed change will add no need determinations and will reduce the unnecessary duplication of mobile MRI scanners. Existing mobile and fixed MRI providers with underutilized equipment need a respite from the backlog of previously approved mobile units plus the surge in new MRI need determinations.

VII. Conclusion

There are at least five CON-approved mobile MRI scanners that are now pending implementation. Also there are numerous mobile MRI scanners that performed less than 3,328 unweighted procedures (mobile MRI performance standards 10A NCAC 14C .2703(a) (1) and (2)). Also consider that mobile MRI scanners certainly have the capacity to perform far more than 3,328 annual unweighted procedures.

No need for additional mobile MRI scanners exists as demonstrated by:

- recent MRI utilization data demonstrating that growth in MRI demand has leveled off
- the number of previously approved mobile scanners that are pending
- the abundance of need determinations for fixed MRI and multi-position scanners

Alliance Imaging Inc. requests that the Proposed 2008 Plan include a statement that no need for additional mobile MRI scanners exists anywhere in the State.

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Technology and Equipment Committee Meeting

August 29, 2007

MRI Material

Material Related To

MRI Petition-2: Ashe Memorial Hospital

Ashe Memorial Hospital

PETITION FOR AN ADJUSTED NEED DETERMINATION FOR ONE FIXED MRI SCANNER FOR ASHE COUNTY IN THE 2008 SMFP

Petitioner:

Ashe Memorial Hospital
200 Hospital Avenue
Jefferson, North Carolina 28640

R.D. Williams, Chief Executive Officer
(336) 846-7101

To:

Medical Facilities Planning Section
Division of Health Service Regulation
2714 Mail Service Center
Raleigh, NC 27699-2714

Requested Change:

Ashe Memorial Hospital (AMH) seeks to provide increased access to fixed MRI services for residents of Ashe County and petitions for an adjusted need determination for one fixed MRI scanner for Ashe County in the 2008 SMFP. There are a number of reasons that justify an adjusted need determination:

- Due to limited mobile access, the hospital is sometimes unable to meet the diagnostic imaging needs of its inpatients and must transfer them to another facility located in another county, further from their home.
- Ashe County has a very high percent of patient emigration seeking available MRI services outside the county.

- The relatively low MRI use rate in Ashe County is indicative of a lack of access to services and of the need for increased access via a full-time fixed MRI scanner at the hospital.
- Given the limited access to mobile MRI services and the inability to increase mobile availability, it is virtually impossible for AMH to experience the growth necessary to trigger a fixed MRI need determination using the standard methodology.
- Ashe County has never had a need determination for a fixed MRI scanner.
- The lack of a need determination for a fixed MRI scanner in Ashe County has negative cost implications for patients and providers.
- Mobile MRI services are not the most effective option from an operational or patient perspective.

Approval of this petition will enable AMH to submit a Certificate of Need application to install the first fixed MRI scanner in Ashe County.

The detailed rationale is described below.

Reasons Supporting Requested Change:

Mobile MRI Access

AMH is a not-for-profit hospital located in the Blue Ridge Mountains, in the northwestern corner of North Carolina. AMH is a rural hospital that has a remarkably sophisticated level of care. Recently, AMH had the honor of being selected the 2006/2007 Outstanding Rural Health Organization of The Year.

AMH began offering MRI services over 14 years ago. As the size of the Medical Staff increased and as patient care protocols trended to regularly utilize diagnostic MRI, AMH responded by contracting with a mobile MRI provider to obtain mobile MRI services. This was the first offering of MRI services in Ashe County and immediately benefited patients. Historically, local residents have demonstrated an increasing demand for MRI services by increasing MRI utilization each year.

Currently, AMH's mobile MRI service is available only two days (Sunday and Wednesday) each week. Due to steadily increasing volumes and the increase in medical practice patterns that utilize MRI as a common diagnostic measure, AMH has requested additional mobile days from its mobile provider. However,

the mobile vendor has been unable to expand its service to AMH due to commitments elsewhere on their routes.

Additionally, as an acute care provider with a busy Emergency Department, AMH needs to have MRI services available 24/7 for inpatients and emergency cases. Due to lack of availability of its mobile scanner, the hospital sometimes is unable to meet the diagnostic imaging needs of some of its inpatients and must transfer them to another facility. Consequently, in 2006, Ashe performed only 75 inpatient MRI procedures compared to 97 inpatient MRI procedures in 2005. In fact, last year, AMH had to transfer ten inpatients to an alternate facility because the mobile MRI scanner was not on-site. Transferring inpatients out of the hospital because of unavailability of a timely MRI scan is a difficult pill to swallow for a small rural hospital, and is costly and inconvenient for the patient and their family.

Based on the Proposed 2008 SMFP data, AMH is 262 weighted MRI scans (484 unweighted MRI scans) away from triggering a need determination for a fixed MRI scanner. However, given the limited access to mobile MRI services and the inability to increase mobile availability, it is extremely difficult for AMH to experience the 40% growth necessary to trigger a fixed MRI need determination. As mentioned previously, due to lack of availability of its mobile scanner, AMH performed only 75 inpatient MRI procedures in 2006 compared to 97 inpatient MRI procedures in 2005.

As stated previously, AMH provides mobile MRI services Sunday and Wednesday each week. While AMH is grateful to have this access, providing mobile MRI services on Sundays is less than ideal. In addition to waiting several days to schedule an exam (there is a 10 day wait for an open MRI appointment as of August 15), patients in the rural South are reluctant to schedule MRI scans on Sundays; therefore, many patients choose to seek alternative, more convenient MRI services outside the county. Consequently, AMH's annualized FY2007 utilization (based on October 2006-June 2007 data) is projected to decrease by nearly 10%.

In summary, despite the best efforts of AMH to improve MRI availability, the current mobile MRI service is insufficient to meet the needs of AMH and of Ashe County residents. The limited MRI access, and inconvenient days of availability are not conducive to enabling AMH to increase its MRI volume, and thereby trigger need for a fixed MRI scanner via the standard SMFP methodology. It is very clear that Ashe County merits an adjusted need determination in recognition of these unique circumstances.

MRI Emigration

Residents of Ashe County are utilizing MRI services, as they and their physicians recognize the benefits of this powerful diagnostic imaging modality. However, each year an increasing number of local patients are forced to travel out of county for MRI services because they are not readily available locally.

AMH, the only hospital in Ashe County, is located in the heart of the Blue Ridge Mountains. The closest fixed MRI provider is located nearly 40 minutes away in Boone. According to patient origin information provided by the Division of Health Service Regulation (DHSR) Planning Section, in 2006, over 73% of Ashe County MRI patients travel to Watauga County for MRI services because they are not available on a full-time basis locally. It is important to consider this statistic from an individual perspective to appreciate the significance. As the following table summarizes, during the past four years nearly 3,000 Ashe County residents have had to travel to Watauga County for MRI services.

Ashe County MRI Emigration

Year	Total Ashe County MRI Patients	Ashe County Patients Traveling to Watauga County	% Emigration to Watauga County
2003	693	496	71.6%
2004	947	633	66.8%
2005	993	651	65.6%
2006	1,508	1,106	73.3%

Source: 2003-2006 MRI Patient Origin Report provided by DHSR Planning Section

Please note that in 2006, 1,106 patients traveled to Watauga County for fixed MRI services. This number nearly doubled from the previous year. This is simply not acceptable. It is unreasonable to expect that residents of Ashe County should have to travel so far outside their own county to obtain timely access to MRI services. Even for a rural mountainous community, MRI is considered a mainstream diagnostic imaging service, and thus should be available locally on a full-time basis. In 2007, there is no good reason why North Carolina residents should travel to a medical center located 40 minutes away in another county. Furthermore, this is not consistent with the State's basic health planning principles of expanding access to services, and of promoting cost-effective approaches.

There are negative implications associated with leaving Ashe County for MRI services. Patients may experience increased costs associated with travel and time spent away from work. Ashe County residents are, on average older than

residents of North Carolina. According to North Carolina demographic estimates, in 2007 approximately 19% of Ashe County residents are 65 and older compared to only 12% in the State[1]. This is important to consider because of the need to provide adequate access to fixed MRI services for medically underserved, i.e. Medicare and Medicaid. Patients may also experience delays obtaining diagnoses. It is inconvenient from a patient perspective to travel out of the county for MRI services that could be expanded locally. Emigration will simply continue if Ashe County fails to implement full-time fixed MRI services amidst its aged population and growing MRI utilization.

Geography

The geography of the region that AMH serves makes it important for the hospital to obtain a full-time fixed MRI scanner. The image below illustrates that the terrain is very mountainous between Ashe and Watauga counties.

Mountainous Ashe County

[1] North Carolina Office of State Budget and Management

Consequently, when the mobile MRI scanner is not on-site at AMH, a patient from Ashe County in need of MRI services must experience long travel times to receive an MRI scan. Winter weather can create dangerous driving conditions, making it even more difficult to travel to a distant county. Many of the roads in and surrounding Ashe County are small, two-lane roads that can become icy or hazardous during inclement weather. In an emergency, it may not always be possible for a patient to be immediately transferred to another facility for MRI services when the mobile scanner is not on-site at AMH. For these reasons, Ashe County residents need an adjusted need determination so that a fixed MRI scanner can be installed at AMH.

The geography of Ashe County can also have a direct impact on AMH's ability to provide mobile MRI services. In 2006, AMH experienced at least three or four days when the mobile MRI scanner could not travel to the hospital because winter weather conditions, e.g. snow and ice. This is significant when considering the fact that the mobile MRI scanner is only scheduled on site for 104 days per year. Further, 2006 was considered a mild winter; there have been previous winters when AMH has lost several more days of mobile MRI access because of treacherous driving conditions.

In the recent past, the SHCC has determined that hospitals located in mountainous regions indeed have special circumstances that may justify an adjusted need determination for a fixed MRI scanner. For example, in 2004, Highlands-Cashiers Hospital submitted a petition for an adjusted need determination based on its inability to obtain mobile MRI services for residents of Macon County. Similarly, AMH, on behalf of Ashe County residents, now seeks an adjusted need determination based on related circumstances.

MRI Use Rate

Increased MRI capabilities have changed the diagnostic approaches to many illnesses and disease states. MRI is the imaging modality of choice for an increasing number of conditions that local physicians see each day. As a result, MRI utilization rates are trending upward nationally, in North Carolina, and despite the limited access, in Ashe County as well. Please see the table below summarizing recent North Carolina utilization rates.

North Carolina MRI Utilization Rate History

Year	State Population	Number of Procedures	Use Rate/1000	Percent Change
2001	8,219,494	485,808	59.10	--
2002	8,336,829	543,635	65.21	10.3%
2003	8,417,255	592,888	70.44	8.0%
2004	8,562,210	653,504	76.32	8.4%
2005	8,663,674	719,447	83.04	8.7%
2006	8,860,341	785,445	88.65	6.8%

Source: Population data from N.C. State Office of Planning
MRI volume data from State Medical Facilities Plans
Totals may not foot due to rounding.

As noted in the table above, in FY2006 the North Carolina MRI use rate was 88.65 (per 1,000 population). Based on population data and MRI patient origin data provided by the DHSR Medical Facilities Planning Section, Ashe County has experienced an MRI use rate significantly lower than that of the State.

In FY2006, Ashe County's MRI use rate was 58.50 (1,508/ (25,778/1,000)), or 34% below the North Carolina MRI use rate. The low use rate in Ashe County is not the result of a lack of need for local fixed MRI services; rather it is indicative of a lack of access to services, and therefore of the need for increased access to fixed MRI scanners for local residents.

Ashe County has a lower MRI use rate compared to the State because the existing, limited mobile MRI service cannot adequately accommodate current demand for MRI services in Ashe County. This is further supported by the increasing number of Ashe County residents traveling out of county or MRI services. Thus, an additional fixed MRI scanner is needed in Ashe County.

SMFP MRI Need Determinations

As stated previously, AMH has provided MRI services for over 14 years. Since the implementation of a MRI need methodology in the 1999 SMFP there have been over 100 individual need determinations for fixed MRI scanners in North Carolina. However, none of these need determined fixed MRI scanner have been awarded in Ashe County.

The MRI need methodology has been modified three times in the six years since its inclusion in the SMFP. Two of these modifications occurred in the 2005 and

2006 SMFP. In the Proposed 2008 SMFP, AMH is 262 weighted MRI scans away from triggering a need determination for a fixed MRI scanner. AMH supports the SMFP MRI need methodology; however, based on the fact that in 2006 an additional 455 Ashe County residents traveled to Watauga County for MRI services, it is virtually impossible for AMH to experience the volume growth (484 unweighted MRI scans) necessary to trigger a fixed MRI need determination.

Adverse Effects on the Population of the Adjustment for a Dedicated Breast MRI Scanner is Not Made

Should this petition not be granted, residents of Ashe County would have to continue with the status quo. AMH would continue providing the existing, limited mobile MRI services. Ashe County patients requiring MRI scans will continue to face lengthy wait times because the mobile MRI scanner is only available on Sunday and Wednesday each week.

The status quo is not a cost effective alternative. Inpatients who need an MRI scan may incur an extended stay to have an MRI scan performed. This, in turn, increases AMH's length of stay and cost of operations. As AMH transitions toward to Critical Access Status, AMH's ability to reduce operating costs will only reduce healthcare costs because the State reimburses Critical Access hospitals based on cost rather than prospective payment. Thus, an adjusted need determination to include one fixed MRI scanner in Ashe County is a cost effective alternative to the status quo.

Mobile MRI scanners provide a valuable service to North Carolina; however, it is not the most cost effective alternative for Ashe County patients. Hospitals and freestanding facilities that host mobile MRI scanners experience higher costs due to the fee that must be paid to the mobile provider for each MRI scan. In FY2006, AMH's total annual cost related to its mobile MRI service was $438,700. Based on AMH's access two days each week, this equates to an average $4,218 each day ($438,700/104 mobile days per year). Unfortunately, these higher costs must be transferred to the patients and payors.

If an adjusted need determination is not granted for Ashe County, patients and providers will experience increased charges and costs, respectively.

No Unnecessary Duplication of Services

Approving this petition will not result in any unnecessary duplication of services in Ashe County. AMH is the only MRI provider in the county. As stated previously, residents of Ashe County do not have timely and convenient access to local fixed MRI services. Patients currently travel at least 40 minutes to Watauga County for fixed MRI services. Should AMH obtain a fixed MRI scanner, it would discontinue its mobile MRI service.

Conclusion

In summary, AMH seeks an adjusted need determination in the 2008 SMFP to include one fixed MRI scanner for Ashe County, based on the following reasons:

- Ashe County has a high percent of patient emigration seeking MRI services outside the county.
- The low use rate in Ashe County is indicative of a lack of access to services and of the need for increased access to a fixed MRI scanner.
- Due to limited mobile access, the hospital is sometimes unable to meet the diagnostic imaging needs of its inpatients and must transfer them to another facility.
- Given the limited access to mobile MRI services and the inability to increase mobile availability, it is virtually impossible for AMH to experience the volume growth necessary to trigger a fixed MRI need determination.
- Ashe County has never had a need determination for a fixed MRI scanner.
- The lack of a need determination for a fixed MRI scanner in Ashe County has negative cost implications for patients and providers.
- Mobile MRI services are not the most effective option from an operational or patient perspective.

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August 3, 2007

Mr. Tom Elkins
Medical Facilities Planning Section
Division of Facility Services
701 Barbour Drive
2714 Main Service Center
Raleigh, NC 27699-2714

Re: Petition for Adjusted MRI Need Determination for Ashe County by Ashe Memorial Hospital, Inc.

Dear Mr. Elkins:

I am writing in support of Ashe Memorial Hospital's petition for an adjusted MRI need determination in Ashe County. As a physician that frequently utilizes MRI for evaluation and diagnosis of many conditions and diseases, I fully support Ashe Memorial's petition for one MRI scanner in Ashe County to be included in the 2008 State Medical Facilities Plan.

MRI capabilities have changed my diagnostic approach to many illnesses and disease states, as I suspect they have for many of the physicians in the medical community. MRI scanning is often the more superior imaging modality for an increasing number of disease states we see each day. But presently, my patients must wait several days to get an MRI scan in Ashe County. It is essential for patients to have timely access to MRI services.

Ashe County is also experiencing increases in population growth and an increasing demand for medical services, especially MRI. In order for the local medical community to remain responsive to patient care needs, it is vital that Ashe County have adequate resources to accommodate demand.

For these reasons, I fully support Ashe Memorial's petition for an adjusted MRI need determination for Ashe County.

Sincerely,

Vickie F. Ingledue, M.D.

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HIGH COUNTRY FAMILY MEDICINE

Kevin J. Kurtz, M.D.
Leigh Bradley, M.D.
Chris Campbell, M.D.

All Physicians are Board Certified by the American Academy of Family Physicians

August 3, 2007

Mr. Tom Elkins
Medical Facilities Planning Section
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For these reasons, I fully support Ashe Memorial's petition for an adjusted MRI need determination for Ashe County.

Sincerely,

Kevin J. Kurtz, M.D.

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August 3, 2007

Mr. Tom Elkins
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Ashe County is also experiencing increases in population growth and an increasing demand for medical services, especially MRI. In order for the local medical community to remain responsive to patient care needs, it is vital that Ashe County have adequate resources to accommodate demand.

For these reasons, I fully support Ashe Memorial's petition for an adjusted MRI need determination for Ashe County.

Sincerely,

Chauncey B. Santos, M.D. P.C.

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Technology and Equipment Committee Meeting

August 29, 2007

MRI Material

Comments Related To

MRI Petition-2: Ashe Memorial Hospital

Ashe Memorial Hospital

SHCC Public Hearing Presentation Comments for
Adjusted Need Determination for Fixed MRI Scanner in Ashe County
July 13, 2007

Good afternoon, my name is R.D. Williams. I am the Chief Executive Officer at Ashe Memorial Hospital. I am here today to speak on behalf of our petition for an adjusted need determination for one fixed MRI scanner in Ashe County to be included in the 2008 State Medical Facilities Plan. We will submit the petition to the Medical Facilities Planning Section by the August 3rd due date.

Ashe Memorial Hospital is a not-for-profit hospital located in the Blue Ridge Mountains, in the north-western corner of North Carolina. Ashe Memorial is a rural hospital that has a remarkably sophisticated level of care. Recently, we had the honor of being selected the 2006/2007 Outstanding Rural Health Organization of The Year. Our hospital is the only provider of MRI services in the county; however, due to mobile MRI availability, access is very limited for local residents. Thus, we are requesting that a need determination be included in the 2008 SMFP for a fixed MRI scanner in Ashe County. There are a number of reasons that justify an adjusted need determination:

Ashe Memorial began offering MRI services over 14 years ago. As the size of the Medical Staff increased and as patient care protocols trended to regularly utilize diagnostic MRI, Ashe Memorial responded by contracting with Alliance Imaging to obtain mobile MRI services. This was the first offering of MRI services in Ashe County and immediately benefited patients. Local residents have demonstrated an increasing demand for MRI services by increasing MRI utilization at Ashe Memorial each year.

Currently, our mobile MRI scanner is available only two days (Sunday and Wednesday) each week. Due to steadily increasing volumes and the increase in medical practice patterns that utilize MRI as a common diagnostic measure, Ashe Memorial Hospital has requested additional mobile days from its mobile provider. However, Alliance Imaging is unable to provide any additional days to us.

Additionally, as an acute care provider with a busy emergency department, Ashe Memorial needs to have MRI services available 24/7 for inpatients and emergency cases. Due to lack of availability of its mobile scanner, the hospital sometimes is unable to meet the diagnostic imaging needs of some of its inpatients and must transfer them to another facility. In fact, last year, we had to transfer several emergency and inpatients to an alternate facility because the mobile MRI service was not on-site. Consequently, in 2006, Ashe performed only 75 inpatient MRI procedures compared to 97 inpatient MRI procedures in 2005.

Ashe Memorial Hospital, the only hospital provider in Ashe County, is located in the heart of the Blue Ridge Mountains. The closest fixed MRI provider is located nearly 40 minutes away in Boone. According to patient origin information provided by the Division of Facility Services Planning Section, over 65% of Ashe County MRI patients must travel this distance for MRI services because they are not readily available locally. This is simply not acceptable from our perspective.

The geography of the region that Ashe Memorial serves makes it important for us to provide fixed MRI services. The terrain is very mountainous between Ashe and Watauga counties. Consequently, a patient from Ashe County in need of MRI services when the mobile MRI scanner is not located at the hospital must experience long travel times to receive an MRI scan. Also, winter weather can create dangerous driving conditions making it even more difficult to travel to fixed MRI sites. Many of the roads in and surrounding Ashe County are small, state roads that can become very icy during inclement weather. In an emergency, the chance exists that a patient may not be immediately transferred to another facility for MRI services. For these reasons, it can be extremely difficult for residents of Ashe County to travel outside of the county for MRI services.

Based on the Proposed 2008 SMFP data, Ashe Memorial is only 484 MRI scans away from triggering a need determination for a fixed MRI scanner. However, given our limited access to mobile MRI services and the inability to increase mobile availability, it is extremely difficult for Ashe Memorial to experience the 40% annual growth necessary to trigger a fixed MRI need determination. As I mentioned previously, due to lack of availability of its mobile scanner, Ashe performed only 75 inpatient MRI procedures in 2006 compared to 97 inpatient MRI procedures in 2005. It is virtually impossible for us to trigger a need determination due our limited mobile MRI access.

Another reason that supports our petition for an adjusted need determination is the fact that MRI utilization in Ashe County is far below the State's average use rate. Ashe County's MRI use rate is less than half of the North Carolina MRI use rate. The low use rate in Ashe County is not the result of a lack of need for local

fixed MRI services; rather it is indicative of a lack of access to services and of the need for increased access to a fixed MRI scanner for local residents. Ashe County's projected population growth further emphasizes the need for access to a fixed MRI scanner; otherwise the county use rate will continue to represent an underserved population.

The lack of a need determination for a fixed MRI scanner in Ashe County has negative cost implications for patients and providers, and thus adversely effects this population. Small rural hospitals, like Ashe Memorial, that host mobile MRI scanners experience higher costs due to the fee that must be paid to the mobile provider for each MRI scan. Unfortunately, these higher costs are often transmitted to the patients. As a current provider of mobile MRI services, Ashe Memorial calculates that, on average, approximately $300 per scan is paid to the mobile MRI provider. Thus, in FY2006, this equates to approximately $369,000 in fees that were paid to our mobile MRI provider. These costs are passed along to consumers.

Finally, aside from the lack of availability, mobile MRI services are not the most effective option from an operational or patient perspective. For example, reliability is not equivalent to that of fixed scanners. Each year Ashe Memorial experiences several days when its mobile MRI scanner is down due to factors associated with travel of the mobile unit. This results in an unnecessary delay of patient access to MRI services. Additionally, physical access to mobile service is less than ideal, because mobile MRI scanners are physically located outside a facility on a concrete pad. Physical access to mobile MRI scanners can be especially problematic in inclement weather. This creates an unnecessary burden for patients, especially the elderly or patients already in pain.

In summary, Ashe Memorial seeks an adjusted need determination to include one fixed MRI scanner in Ashe County in the 2008 SMFP, based on the following reasons:

- Due to limited mobile access, the hospital is sometimes unable to meet the diagnostic imaging needs of its inpatients and must transfer them to another facility.
- The low use rate in Ashe County is indicative of a lack of access to services and of the need for increased access to a fixed MRI scanner.
- The lack of a need determination for a fixed MRI scanner in Ashe County has negative cost implications for patients and providers
- Mobile MRI services are not the most effective option from an operational or patient perspective.
- Given our limited access to mobile MRI services and the inability to increase mobile availability, it is virtually impossible for Ashe Memorial

to experience the 40% annual growth necessary to trigger a fixed MRI need determination.

We feel there is a clear need for an additional fixed MRI scanner in Ashe County. We hope you will support us in this effort by approving this petition for an adjusted need determination. Thank you.

Top of Document

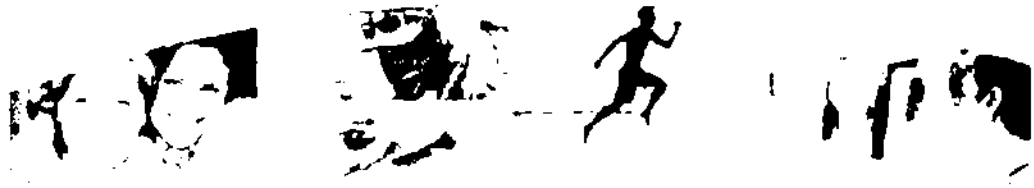
Technology and Equipment Committee Meeting

August 29, 2007

MRI MATERIAL

Material Related to

MRI Petition – 3: Greensboro Orthopaedics, P.A.



PETITION FOR AN ADJUSTED NEED DETERMINATION FOR ONE FIXED MRI SCANNER FOR GUILFORD COUNTY

Petitioner:

Greensboro Orthopaedics, P.A.
1401 Benjamin Parkway
Greensboro, NC 27408-4518

John S. Nosek, MPA, CMPE
Executive Director
336-545-5000

To:

Medical Facilities Planning Section
Division of Health Service Regulation
2714 Mail Service Center
Raleigh, NC 27699-2714

Requested Change:

Greensboro Orthopaedics, P.A. (GOC) seeks an adjusted MRI need determination, specifically to include one fixed MRI scanner in Guilford County in the 2008 State Medical Facilities Plan (SMFP).

There are a number of reasons that justify an adjusted need determination

- The MRI utilization in Guilford County is well above the State's average use rate
- Guilford County has an unreasonably low ratio of fixed MRI scanners to population compared to other similar counties.
- Guilford County had the second highest mobile utilization in FY2006 of all North Carolina counties, and its proportion of mobile MRI scans to total MRI scans is increasing.
- Of the 12 counties with fixed MRI need determinations in the Proposed 2008 SMFP, nine have a lower population to fixed MRI ratio than does Guilford County.
- The percentage of Guilford County residents who obtain MRI scans in other counties has been steadily increasing the past three years.
- Because of the high level of mobile MRI utilization in Guilford County, the lack of a need determination for an additional fixed MRI scanner in Guilford County has negative cost implications for patients and providers, thus adversely effects this population.
- Mobile MRI services are not the most effective option from an operational or patient perspective.

Approval of this petition will enable any eligible applicant the opportunity to submit competitive Certificate of Need applications proposing the best plan for addition of a fixed MRI scanner in Guilford County.

The detailed rationale is described below.

Mobile MRI Utilization

Currently, Guilford County has four providers that are exclusively mobile sites, Greensboro Orthopaedics, Guilford Neurosurgical, High Point Orthopaedics and Southeastern Orthopaedic Specialists. In FY2006, these four providers performed 11,988 mobile MRI procedures. In addition, three other mobile MRI host sites performed an additional 5,685 mobile MRI procedures, for a total of 17,673 mobile MRI procedures performed in Guilford County. This is the second highest utilization of mobile MRI services in North Carolina, behind only Mecklenburg County, which has a population nearly twice as large as that of Guilford County. The table below provides mobile MRI utilization for the ten counties with the highest mobile MRI utilization in FY2006.

FY2006 Mobile MRI Utilization
Top 10 Counties

County	Mobile
MECKLENBURG	20,118
GUILFORD	17,673
WAKE	10,645
NEW HANOVER	10,362
FORSYTH	7,356
MOORE	6,664
CATAWBA	6,592
GASTON	4,203
ONSLOW	3,659
RUTHERFORD	3,360

Source: Proposed 2008 SMFP

The FY2006 data is not an anomaly. For the past three years, mobile utilization in Guilford County has steadily increased. In fact, mobile utilization in Guilford County triggered a need for a fixed MRI scanner in the 2001, 2002, 2003 and 2005 SMFP. The following table provides historical mobile MRI utilization for Guilford County.

Guilford County Historical Mobile MRI Utilization
FY2000-FY2006

Year	Mobile Utilization	% Increase
2000	6,217	--
2001	8,905	43.2%
2002	11,058	24.2%
2003	13,194	19.3%
2004	14,680	11.3%
2005	15,307	4.3%
2006	17,673	15.5%

Source: 2002-2007 SMFP, Proposed 2008 SMFP

As shown in the previous table, mobile MRI utilization in Guilford County experienced an average annual increase of over 184% from 2000 to 2006. This is a direct indication of the need for increased access to fixed MRI services. Clearly, special circumstances exist in Guilford County with regard to utilization of mobile MRI services that necessitate the need for additional fixed MRI access. GOC believes an adjusted need determination for one additional fixed MRI scanner in Guilford County will provide much needed local services that will be highly utilized.

Fixed MRI Scanners in Guilford County

In addition to having high utilization of MRI services, demographic data also demonstrates a clear need for increased access to fixed MRI services in Guilford County.

Currently, there are ten operational MRI scanners in Guilford County. This is disproportionate to the growing population in Guilford County. Comparatively, of the seven most populous counties in North Carolina, Guilford County has the second worst ratio of fixed MRI scanners to population. Please refer to the table below.

Fixed MRI Scanner to Population Ratio
Most Populous North Carolina Counties

County	2006 Population	2011 Population	% Change	Total Fixed Magnets	Magnet to Population Ratio
Wake	789,969	933,711	18.2%	11	71,815
Guilford	449,071	481,855	7.3%	10	44,907
Cumberland	306,545	314,202	2.5%	7	43,792
Mecklenburg	826,897	952,975	15.2	19	43,521
Forsyth	331,851	356,188	7.3%	14	23,704
Buncombe	221,327	238,214	7.6	10	22,133
Durham	246,825	266,860	8.1%	12	20,569

Source: Proposed 2008 SMFP, NC State Demographics (

Forsyth County (which is adjacent to Guilford County) has a far more favorable ratio of fixed MRI scanners to population. Notably, however, in 2006 Guilford County had a population 30% higher than that of Forsyth County. Also, Buncombe County, which has a population less than half that of Guilford County, has the same number of fixed MRI scanners (10) as Guilford County. Both of these examples are inconsistent with the principle of equitable access to healthcare services in North Carolina.

As the population continues to increase and the medical community continues to grow, there is no indication that the trending increase of MRI services in Guilford County will change in the near future.

Guilford County MRI Use Rate

Improved MRI technology and capabilities have enhanced the clinical diagnostic approaches to many illnesses and disease states. As a result, MRI is often the imaging modality of choice for an increasing number of conditions that local physicians seek to diagnose each day. As a result, MRI utilization rates have greatly increased. The North Carolina MRI utilization rate was 88.7 procedures per 1,000 population in 2006. In the last two years (2004-2006) the North Carolina MRI use rate increased by 30%.

MRI utilization rates for individual counties in North Carolina are trending upward as well. Residents of Guilford County and their physicians recognize the valuable benefits of MRI services. As a result, MRI services are highly utilized in Guilford County. The Proposed 2008 SMFP shows Guilford County as having a higher MRI use rate compared to the North Carolina average.

2006 MRI Use Rate per 1,000 Population

	MRI Procedures	Population	MRI Use Rate
Guilford County	52,235	449,071	116.3
North Carolina	786,150	8,860,341	88.7

Source: Proposed 2008 SMFP, NC State Demographics (http://demog.state.nc.us/) updated 2006.

As shown above, Guilford County provides MRI services over 31% above the State average. In fact, Guilford County has the 14th highest MRI use rate per 1,000 population of the 100 counties in North Carolina. Please refer to the table below.

2006 MRI Use Rates by County

County	# of Procedures			2006 Population	MRI Use Rate
	Fixed	Mobile	Total		
MOORE	12,704	6,664	19,368	82,288	235.4
ORANGE	25,610	--	25,610	123,762	206.9
FORSYTH	60,024	7,356	67,380	331,851	203.0
BUNCOMBE	40,405	156	40,561	221,327	183.3
DURHAM	43,735	1,290	45,025	246,825	182.4
PITT	24,554	843	25,397	146,398	173.5
HERTFORD	2,036	2,018	4,054	23,901	169.6
CHOWAN	--	2,438	2,438	14,677	166.1
CABARRUS	24,910	575	25,485	157,176	162.1
NEW HANOVER	16,292	10,362	26,654	184,116	144.8
CATAWBA	13,910	6,592	20,502	151,126	135.7
CRAVEN	12,181		12,181	95,566	127.5
IREDELL	16,850	308	17,158	145,232	118.1
GUILFORD	34,562	17,673	52,235	449,071	116.3

Source: Proposed 2008 SMFP, NC State Demographics (http://demog.state.nc.us/) updated 2006

Below is a table showing the North Carolina counties that had the most MRI scans during FY 2006. As shown, Guilford County hosted the 4th largest number of MRI scans of all 100 North Carolina counties.

Highest Volume MRI Counties in North Carolina

County	Fixed	Mobile	Total
MECKLENBURG	68,428	20,118	88,546
FORSYTH	60,024	7,356	67,380
WAKE	45,047	10,645	55,692
GUILFORD	34,562	17,673	52,235
DURHAM	43,735	1,290	45,025
BUNCOMBE	40,405	156	40,561
CUMBERLAND	28,410	383	28,793
NEW HANOVER	16,292	10,362	26,654
ORANGE	25,610	0	25,610
CABARRUS	24,910	575	25,485
PITT	24,554	843	25,397

Sources: 2008 SMFP

This is a clear indication that MRI is an important and highly utilized service for Guilford County.

In addition to being North Carolina's 3rd most populous county, Guilford County is also one of the State's primary health care centers. Guilford County hosts large medical centers, and is home to a large number of physicians and other provider professionals (such as Greensboro Orthopaedics), representing practically every medical specialty and sub-specialty. These providers serve not only residents of Guilford County, but also residents of neighboring counties and residents from throughout North Carolina and adjacent states. As a result, it is important that the county's resources have the capacity to accommodate this current and growing demand.

Further, of the 12 North Carolina counties for which the Proposed 2008 SMFP indicates a need determination for an additional fixed MRI scanner, nine counties have at least one fixed MRI scanner, and of those, six have a lower population to fixed MRI scanner ratio than does Guilford County. Please see the table below.

Proposed 2008 SMFP MRI Need Determination Counties

County	2006 Population	2011 Population	% Change	Total Fixed Magnets	Magnet to Population Ratio	Need Determination
Orange	123,762	131,195	6.0	7	17,680	1
Forsyth	331,851	356,188	7.3	14	23,704	1
Craven	95,566	99,884	4.5	3	31,855	1
Jackson	36,312	38,478	6.0	1	36,312	1
Surry	73,000	75,230	3.1	2	36,500	1
Vance	43,925	45,204	2.9	1	43,925	1
Guilford	449,071	481,855	7.3	10	44,907	0
Lenoir	58,170	57,910	-0.4	1	58,170	1
Carteret	63,557	66,856	5.2	1	63,557	1
Wilkes	66,924	68,130	1.8	1	66,924	1

Source: Proposed 2008 SMFP, NC State Demographics (http://demog.state.nc.us/) updated 2006

In addition, the percentage of Guilford County residents who obtain MRI scans in other counties has been steadily increasing the past three years. As shown on the table below, during FY2006 over 13% of Guilford County residents had to obtain an MRI scan outside the county. This represents a 45% increase from FY2003.

Out-of-county MRI Scans
Guilford County Residents
FY2003 - FY2005

Year	% of Total Scans
2003	9.1
2004	9.7
2005	13.1
2006	13.2

Source: MRI Patient Origin Data, Medical Facilities Planning Section

These data are a strong indication of the limited access to MRI services within Guilford County. In order to provide quality and timely care it is essential that Guilford County

have an inventory of fixed MRI scanners that is proportionate to the population seeking such services.

No Unnecessary Duplication of Services

Greensboro Orthopaedics has established that Guilford County currently has an unreasonably low ratio of fixed MRI scanners to population compared to other similar counties. This petition also contains evidence that a growing percentage of the MRI scans performed on Guilford County residents are obtained in another county. This provides further evidence that an additional fixed MRI scanner is needed in Guilford County. Also, members of the medical communities in Guilford County indicate that an additional fixed MRI scanner in the local community will increase access, alleviate capacity constraints on existing providers, and will better serve the community's MRI needs. Clearly therefore, addition of another fixed MRI scanner in Guilford County is not unnecessary duplication. Similarly, Guilford County had the second highest mobile utilization in FY2006 of all North Carolina counties. This is a direct indication of the need for increased access to fixed MRI services.

Adverse Effects of No Adjustment to the Need Determination

Should this petition not be granted, Guilford County would have to continue with the status quo. The existing fixed and mobile providers would continue providing the existing MRI services with their present inadequate capacity. However, given the steady increase of MRI utilization in Guilford County, this is not a viable alternative. The table below provides historical MRI utilization in Guilford County.

Guilford County Historical MRI Utilization
FY2001-FY2006

	MRI Procedures	% Increase
2001	40,489	21.1
2002	42,251	4.4
2003	46,244	9.5
2004	50,912	10.1

2005	53,569	5.2%
2006	52,235	-2.5%

Source: 2003 – 2007 SMFP, Proposed 2008 SMFP

In the past five years, Guilford County has experienced a total increase in MRI procedures of over 29%. As previously stated in this petition, the mobile MRI utilization has increased much faster, 184%, during the same five-year period. As a result, the proportion of mobile MRI scans performed in Guilford County has risen from 18% of total MRI scans in 2001, to nearly 34% of total MRI scans in 2006. Please see the table below.

Guilford County Mobile MRI Utilization Ratio

	Mobile Utilization	Total Utilization	% Mobile of Total
2000	6,217	33,428	18.6%
2001	8,905	40,489	22.0%
2002	11,058	42,251	26.2%
2003	13,194	46,244	28.5%
2004	14,680	50,912	28.8
2005	15,307	53,569	28.6
2006	17,673	52,235	33.8

Source: 2003 – 2007 SMFP, Proposed 2008 SMFP

As previously discussed, the ratio of fixed MRI providers to population is already less favorable than comparative and surrounding counties, and Guilford County currently has the second largest mobile MRI volume in the State. These factors combined make the status quo unacceptable from a planning and patient access perspective.

Since 1997, Greensboro Orthopaedics has provided mobile MRI services in Guilford County. Currently, a mobile MRI scanner is on site and operational five days each week. While Greensboro Orthopaedics values the services a mobile MRI scanner provides to the community, it is not the most effective option from an operational, patient, or cost perspective. First, reliability is not equivalent to that of fixed scanners. Each year, GOC experiences several days when its mobile MRI scanner is down or due to

factors associated with travel of the mobile unit. This results in an unnecessary delay of patient access to MRI services. Second, physical access to mobile service is less than ideal, because mobile MRI scanners are physically located outside a facility on a concrete pad. Access to mobile MRI scanners can be especially problematic in inclement weather, or during days of extreme hot or cold temperatures. This creates an unnecessary burden for patients, especially the elderly or patients already in pain.

Existing providers of mobile MRI services in Guilford are reaching practical operating capacity. For example, Greensboro Orthopaedic's mobile MRI utilization, although the highest in the county, has been relatively flat for the last two years, compared to the growth in previous years.

Greensboro Orthopaedics, P.A.
Mobile MRI Utilization
FY2001-FY2006

Year	MRI Scans	% Increase
FY2001	2,646	--
FY2002	4,238	60.2
FY2003	4,582	8.1
FY2004	5,128	11.9
FY2005	5,288	3.1
FY2006	5,526	4.5

Source: 2005-2007 SMFPs, Proposed 2008 SMFP

This is due to the high utilization of mobile MRI services at Greensboro Orthopaedics, and the lack of additional capacity. As stated previously, GOC has operational access to a mobile MRI scanner five days each week. Due to the current utilization of its existing mobile MRI services and the amount downtime experienced each year, GOC is not able to accommodate the demand for its MRI services. GOC's experience is not unusual as mobile MRI capacity is limited throughout the State.

Finally, there are negative cost implications associated with maintaining the status quo in Guilford County. As described previously, Guilford County performed the greatest number of mobile MRI procedures in North Carolina in 2006 (17,673 mobile MRI procedures). Hospitals and freestanding facilities that host mobile MRI scanners experience higher costs due to the fee that must be paid to the mobile provider for each

MRI scan. Unfortunately, these higher costs are often transmitted to the patients. As a current provider of mobile MRI services, GOC estimates that, on average in Guilford County, approximately $300 per scan is paid to the mobile MRI provider. Thus, in FY2006, this equates to approximately $5,302,000 in fees that were paid to mobile providers in Guilford County. These costs are passed along to consumers.

Mobile MRI scanners provide a valuable service to Guilford County, however, it is not the most cost effective alternative for patients. If an adjusted need determination is not granted for Guilford County, patients and providers will continue to experience increased charges and costs, respectively.

Conclusion:

In summary, Greensboro Orthopaedics, P.A. seeks an adjusted need determination to include one fixed MRI scanner in Guilford County in the 2008 SMFP, based on the following reasons:

- The MRI utilization in Guilford County is well above the State's average use rate.
- Guilford County has an unreasonably low ratio of fixed MRI scanners to population compared to other similar counties.
- Guilford County had the second highest mobile utilization in FY2006 of all North Carolina counties, and its proportion of mobile MRI scans to total MRI scans is increasing.
- Of the 12 counties with fixed MRI need determinations in the proposed 2008 SMFP, nine have a lower population to fixed MRI ratio than does Guilford County.
- The percentage of Guilford County residents who obtain MRI scans in other counties has been steadily increasing the past three years.
- Because of the high level of mobile MRI utilization in Guilford County, the lack of a need determination for an additional fixed MRI scanner in Guilford County has negative cost implications for patients and providers, thus adversely effects this population.
- Mobile MRI services are not the most effective option from an operational or patient perspective.

We feel there is a clear need for an additional fixed MRI scanner in Guilford County. We hope you will support us in this effort by approving this petition for an adjusted

need determination. Thank you for providing us with the opportunity to present this important community issue.

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Technology and Equipment Committee Meeting

August 29, 2007

MRI MATERIAL

Material Related to

MRI Comments – 3: Greensboro Orthopaedics, P.A.

Greensboro PH
7-20-07
MRI
Tom

Medical Facilities
Planning Section

SHCC Public Hearing Presentation Comments for
Adjusted Need Determination for Fixed MRI Scanners in Guilford County
July 20, 2007

Good afternoon, my name is David Meyer. I am a consultant to Greensboro Orthopaedics. I am here today to speak on behalf of their petition for an adjusted need determination for one fixed MRI scanner in Guilford County to be included in the 2008 State Medical Facilities Plan.

Approval of this petition will enable any eligible applicant the opportunity to submit competitive Certificate of Need applications proposing the best plan for addition of a fixed MRI scanner in Guilford County.

There are a number of reasons that justify an adjusted need determination in Guilford County:

Historically, mobile MRI utilization has played an important role in determining need for fixed MRI scanners in Guilford County. Mobile utilization in Guilford County triggered a need for a fixed MRI scanner in the 2001, 2002, 2003 and 2005 SMFPs.

Currently, Guilford County has four MRI providers that are exclusively mobile sites. In FY2006, these four providers performed 11,988 mobile MRI procedures. In addition, three other mobile MRI host sites performed an additional 5,685 mobile MRI procedures. This is the second highest utilization of mobile MRI services of any county in the State. The scans performed at these sites are indicative of a greater need for at least another fixed MRI scanner based in Guilford County. Clearly, special circumstances exist in Guilford County with regard to utilization of mobile MRI services that necessitate the need for additional fixed MRI access.

Second, Guilford County has an unreasonably low ratio of fixed MRI scanners to population compared to other similar counties. Specifically, of the seven most populous counties in North Carolina (counties with populations exceeding

days when its mobile MRI scanner is down due to factors associated with travel of the mobile unit. This results in an unnecessary delay of patient access to MRI services. Additionally, physical access to mobile service is less than ideal, because mobile MRI scanners are physically located outside a facility on a concrete pad. Physical access to mobile MRI scanners can be especially problematic in inclement weather, or during days of extreme hot or cold temperatures. This creates an unnecessary burden for patients, especially the elderly or patients already in pain.

In summary, Greensboro Orthopaedics seeks an adjusted need determination to include one fixed MRI scanner in Guilford County in the 2008 SMFP, based on the following reasons:

- Guilford County had the second highest mobile utilization in FY2006 of all North Carolina counties.
- Guilford County has an unreasonably low ratio of fixed MRI scanners to population compared to other similar counties.
- The MRI utilization in Guilford County is well above the State's average use rate.
- Of the 12 counties with fixed MRI need determinations in the proposed 2008 SMFP, nine have a lower population to fixed MRI ratio than does Guilford County.
- Because of the high level of mobile MRI utilization in Guilford County, the lack of a need determination for an additional fixed MRI scanner in Guilford County has negative cost implications for patients and providers, thus adversely effects this population.
- Mobile MRI services are not the most effective option from an operational or patient perspective.

We feel there is a clear need for an additional fixed MRI scanner in Guilford County. We hope you will support us in this effort by approving this petition for an adjusted need determination. Thank you for providing us with the opportunity to discuss this important issue.

Top of Document

Technology and Equipment Committee Meeting

August 29, 2007

MRI MATERIAL

Material Related to

MRI Petition – 4: HOPE, A Women's Cancer Center

Hope
A Women's Cancer Center

PETITION FOR AN ADJUSTED NEED DETERMINATION FOR DEDICATED BREAST MRI SCANNER FOR HSA I

Petitioner:

Hope – A Women's Cancer Center
100 Ridgefield Court
Asheville, NC 28806
(828) 670-8403

David J. Hetzel M.D., FACOG, FACS
Nathan Williams, M.D., FACS
Tim Vanderkwaak, M.D., FACOG, FACS
C. Blair Harkness, M.D., FACOG

Requested Change:

Hope – A Women's Cancer Center is dedicated to providing the finest Gynecologic and Breast Oncology services in western North Carolina and petitions for an adjusted need determination for one Dedicated Breast MRI scanner for HSA I in the 2008 SMFP.

Reasons Supporting Requested Change:

Breast cancer is the most common cancer among women. Every three minutes a woman in the United States is diagnosed with breast cancer. In 2006, an estimated 212,920 new cases of invasive breast cancer are expected to be diagnosed, along with 61,980 new cases of non-invasive breast cancer. And

40,970 women are expected to die in 2006 from this disease[1]. This risk has increased dramatically over the past four decades. Today the chance of developing invasive breast cancer at some time in a woman's life is about 1 in 7. In 1960, the chance of developing invasive breast cancer was only 1 in 20. Women living in North America have the highest rate of breast cancer in the world[2].

The North Carolina Central Cancer Registry (NCCCR) projected that 6,335 women in North Carolina would be diagnosed with breast cancer in 2005. In HSA I the NCCCR projects 1,140 breast cancer cases or almost 18% of the total North Carolina breast cancer cases in 2005[3].

For breast cancer, early detection saves lives. For example, almost 98 percent of women who are diagnosed with breast cancer in the earliest stage survive the disease, whereas only 26 percent survive if the disease is diagnosed in the most advanced stage. The opportunity for disease control and for reducing the number of cancer deaths rests with prevention and early detection so that treatment of the disease can be effective. This is the foundation of our petition for a dedicated breast MRI scanner in HSA I.

Hope is aware that the 2006 State Medical Facilities Plan included an adjusted need determination for a dedicated and specialized breast MRI scanner. This adjusted need determination was the result of a petition submitted by Novant Health in Winston-Salem. This petition was based on American Cancer Society (ACS) Guidelines that were released in 2003 stating women might benefit from additional screening strategies beyond those offered to women at average risk.

The evidence that was available at the time of the 2003 ACS Guidelines was insufficient to justify recommendations for additional screening approaches, such as MRI. The ACS recommended that decisions about screening options for women at significantly increased risk of breast cancer be based on shared decision making after a review of potential benefits, limitations, and harms of different screening strategies and the degree of uncertainty about each.

Nonetheless, the State Health Coordinating Council (SHCC) and North Carolina Division of Health Service Regulation (DHSR) staff determined that expanding dedicated breast MRI imaging in the State could be important. The Breast Clinic MRI, LLC (Forsyth County, HSA II) was awarded a CON for the dedicated breast MRI scanner; that project is currently under development.

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[1] www.breastcancer.org
[2] American Cancer Society
[3] North Carolina Central Cancer Registry, 2005 Profiles

New evidence on breast MRI screening has become available since the ACS last issued guidelines in 2003. A guideline panel has reviewed this evidence and developed new recommendations for women at different levels of risk.

According to the ACS, women with a genetic predisposition to breast cancer, and/or those with a family history of the disease, should undergo annual MRI screening along with routine mammograms. Specific guidelines were released in March of 2007 identifying the women who should have a breast MRI scan. These guidelines include:

- Those who are BRCA mutation carriers;
- Women with first-degree relatives who are BRCA mutation carriers;
- Women with a 20% to 25% lifetime risk of breast cancer based on family history;
- Women who had radiation treatment to the chest between the ages of 10 and 30; and
- Women with Li-Fraumeni, Cowden, or Bannayan-Riley-Ruvalcaba syndromes[4].

The guideline states that, for high-risk women, screening with MRI and mammography should begin at age 30. These new guidelines demonstrate that a much larger population can benefit from breast MRI screening compared to the 2003 guidelines. A copy of the ACS report has been included with this petition. Based on the 2007 ACS guidelines, geography and demographic data, need for a local dedicated breast MRI scanner is strongly indicated to most appropriately serve residents of HSA I.

As stated previously, one guideline for identifying women who should have a breast MRI scan are those who are BRCA mutation carriers. The prevalence of BRCA mutations is estimated to be between 1/500 and 1/100 in the general population[4]. This equates to approximately 445 Buncombe County residents and over 2,700 women in HSA I who could benefit from an annual breast MRI scanner. Please refer to the table below.

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[4] Saslow et al for the American Cancer Society Breast Cancer Advisory Group. American Cancer Society Guidelines with MRI as an Adjunct to Mammography. CA Cancer J Clin 2007; 57:75-89
Petruccelli N, Daly MB, Culver JOB, et al. BRCA1 and BRCA2 Hereditary Breast/Ovarian Cancer. Gene Reviews. December 28, 2006.

2007 Estimated BRCA Mutation Carriers - HSA I

	2007
ALLEGHANY	22
ASHE	51
WATAUGA	87
WILKES	137
AVERY	37
ALEXANDER	73
CALDWELL	159
MITCHELL	33
BURKE	180
CATAWBA	307
YANCEY	37
MCDOWELL	89
CLEVELAND	198
RUTHERFORD	128
MADISON	41
BUNCOMBE	445
HENDERSON	203
POLK	39
HAYWOOD	117
TRANSYLVANIA	60
SWAIN	28
JACKSON	75
GRAHAM	16
MACON	67
CHEROKEE	54
CLAY	20
HSA I Total Population	**2,703**

Source: 2007 population provided by NC Office of State Budget and Management / 500

The 2007 ACS Guidelines also state that women with a 20% to 25% lifetime risk of breast cancer based on family history should have an annual breast MRI scan. According to the American Cancer Society, 2% of women have a family history suggestive of breast cancer inheritance. While 2% may sound nominal, this equates to as many as 2,337 women in Buncombe County and 13,747 women in HSA I. Please refer to the following table.

Women with 20% to 25% Lifetime Risk of Breast Cancer Based on Family History 2007 Population, HSA I

	2007
ALLEGHANY	112
ASHE	261
WATAUGA	436
WILKES	678
AVERY	166
ALEXANDER	368
CALDWELL	805
MITCHELL	161
BURKE	885
CATAWBA	1,541
YANCEY	189
MCDOWELL	438
CLEVELAND	1,000
RUTHERFORD	654
MADISON	209
BUNCOMBE	2,337
HENDERSON	1,049
POLK	201
HAYWOOD	593
TRANSYLVANIA	322
SWAIN	148
JACKSON	375
GRAHAM	84
MACON	351
CHEROKEE	280
CLAY	106
HSA I Total Population	**13,747**

Source: NC Office of State Budget and Management

Based on only two of the 2007 ACS Guidelines, approximately 16,450 women in HSA I are indicated for an annual breast MRI scan. The 2007 ACS Guidelines also recommend annual breast MRI screening for women with first-degree relatives who are BCRA mutation carriers, women who had radiation treatment to the chest between the ages of 10 and 30 and women with Li-Fraumeni, Cowden, or Bannayan-Riley-Ruvalcaba syndromes. Clearly, need exists for increased access to convenient breast MRI imaging in western North Carolina.

In addition to the 2007 ACS Guidelines, a March 2007 study in the New England Journal of Medicine (NEJM) indicates that for women who have newly diagnosed cancer in one breast, MRI can find tumors in the other breast that mammograms miss. Even after careful clinical and mammographic evaluation, cancer is found in the contra lateral breast in up to 10% of women who have received treatment for unilateral breast cancer[5]. The study, conducted at 25 medical centers, included 969 women with recently diagnosed cancer in one breast and a normal mammogram on the other. All were given MRI scans, which discovered cancers in the supposedly healthy breast in 30 women, 3.1 percent of the group. Nearly all cancers were at an early stage, and were treated at the same time as the cancers that were originally discovered. Thus, breast MRI can help women who already have one cancer by detecting a hidden tumor in the other breast, enabling them to have both cancers treated at once instead of having to go through treatment all over again when the second tumor is finally detected. MRI can also be used to evaluate the rest of the breast tissue prior to a lumpectomy to detect whether the cancer has spread.

The ACS states "there are substantial concerns about limited access to high-quality MRI breast screening services for women with familial risk. With many communities not providing MRI screening, it is recognized that these recommendations may generate concerns in high-risk women who may have limited access to this technology."

Based on the 2007 SMFP, residents of HSA II currently have local access to dedicated breast MRI services in Charlotte. Residents in HSA III will have soon have local access to dedicated breast MRI services in Winston-Salem pursuant to the 2006 SMFP adjusted need determination and subsequently approved CON for The Breast Clinic MRI, LLC. Residents of HSA I do not have local access to dedicated breast MRI services. It is well known that it is very difficult for residents of western North Carolina to travel long distances for healthcare services. Furthermore, the 2007 ACS Guidelines identify a greater population of women who can benefit from breast MRI (the 2003 ACS data were merely recommendations). A dedicated breast MRI scanner is needed in HSA I to serve the residents of western North Carolina.

Some data is available on the cost-effectiveness of breast MRI screening. One recent study modeled cost-effectiveness for adding MRI to mammography screening for women of different age groups who carry a BRCA1 or BRCA2 mutation. The authors concluded that the cost per quality-adjusted life year

[5] Lehman et al. MRI Evaluation of the Contralateral Breast in Women with Recently Diagnosed Breast Cancer. New England Journal of Medicine Volume 356:1295-1303 March 29, 2007 Number 13

saved for annual MRI plus film mammography, compared with annual film mammography alone, varied by age and was more favorable in carriers of a mutation in BRCA1 than BRCA2 because BRCA1 mutations confer higher cancer risk and higher risk of more aggressive cancers, than BRCA2 mutations[6]. Estimated cost per quality of life year for women aged 35 to 54 years was $55,420 for women with BRCA1 mutation and $130, 695 for women with BRCA2 mutation.

The ACS states that the ability of MRI to detect breast cancer is directly related to high-quality imaging, particularly the signal-to-noise-ratio, as well as spatial resolution of the MRI image. Thus, it is necessary to implement local dedicated breast MRI technology in HSA I to serve western North Carolina residents. The existing, general purpose MRI scanners currently in HSA I are not sufficient to provide the benefits of dedicated breast MRI screening. Specifically, the ability to perform MRI-guided biopsy is absolutely essential to offering screening MRI[7]. The American College of Radiology (ACR) is currently developing an accreditation process for performing breast MRI, and, in addition to the performance of high spatial resolution images, the ability to perform MRI intervention (i.e. needle localization and/or biopsy) will be essential in order to obtain accreditation by ACR. This guideline will likely be available in 2007.

Hope currently has resources in place to effectively provide dedicated breast MRI services. Hope is a skilled women's cancer center, experienced in treating women with cancer such as breast, ovarian, and cervical cancer. Hope has provided women's healthcare services to patients of western North Carolina for over 14 years. Hope currently provides an array of diagnostic services for its patients, including mammography, stereotactic breast biopsy, chest X-ray, bone densitometry, and ultrasound.

Hope physicians are primary investigators for the Gynecologic Oncology Group in western North Carolina. The GOG is the primary study group for women's cancers in the United States. Hope is also a cooperative group with the American College of Surgeons - Oncology Group and participates in breast cancer trials. In addition Hope participates in other clinical trials through Cancer Trials Support Unit which is a clearinghouse to facilitate enrollment in clinical trials that are sponsored by other cooperative groups. The National Cancer Institute (NCI) works with the GOG, other cooperative groups and most of the major cancer centers to develop new treatments or fine-tuning existing ones.

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[6] Antoniou A, Pharoah PD, Narod S, et al. Average risks of breast and ovarian cancer associated with BRCA1 or BRCA2 mutations detected in case series unselected for family history: a combined analysis of 22 studies. Am J hum Genet 2003; 72:1117-1130.

[7] Saslow et al for the American Cancer Society Breast Cancer Advisory Group. American Cancer Society Guidelines with MRI as an Adjunct to Mammography. CA Cancer J Clin 2007; 57:75-89

These changes usually lead to improving the standard of care. In short, Hope, with its clinical research program dedicated to the advancement of women's cancer care through clinical research and education, is an ideal location for implementation of dedicated breast MRI technology.

Adverse Effects on the Population if the Adjustment for a Dedicated Breast MRI Scanner is Not Made

If this petition for an adjusted need determination for a dedicated breast MRI scanner in HSA I is not granted, residents of western North Carolina will be denied local access to state-of-the-art technology that is proven to be beneficial for a specific patient population. This petition identifies at least 16,450 western North Carolina residents who can benefit from this technology, according to the 2007 ACS Guidelines.

In addition, failure to approve this petition will deprive the estimated 1,140 women[8] who have newly diagnosed cancer in one breast, the opportunity to readily identify tumors in the other breast that mammograms miss.

Lives could be saved and treatment courses modified through the use of breast MRI scans to detect breast cancer more accurately. Failure to allow the implementation of this technology in HSA I may increase long-term health costs, because existing modalities are less likely to detect cancer compared to MRI.

No Unnecessary Duplication of Services

Approving this petition will not result in any unnecessary duplication of services in HSA I. As stated previously, residents of western North Carolina do not have timely and convenient access to local dedicated breast MRI services. Additionally, the ACS Guidelines stress the ability of MRI to detect breast cancer is directly related to high-quality imaging, particularly the signal-to-noise-ratio, as well as spatial resolution of the MRI image. Additionally, the ability to perform MRI-guided biopsy is absolutely essential to offering screening MRI. General purpose MRI scanners do not offer this technology. Thus, it is necessary to implement dedicated breast MRI technology in HSA I to serve western North Carolina residents. The existing, general purpose MRI scanners currently in HSA I are not sufficient to provide the benefits of dedicated breast MRI screening.

[8] North Carolina Central Cancer Registry estimated 2005 cancer cases in HSA I.

Conclusion

In summary, Hope – A Women's Cancer Center seeks an adjusted need determination in the 2008 SMFP to include one dedicated breast MRI scanner for HSA I, based on the following reasons:

- The 2007 ACS Guidelines identify specific groups of women who should have a breast MRI scan.
- Hope identifies at least 16,450 western North Carolina residents who can benefit from this technology, according to the 2007 ACS Guidelines.
- The New England Journal of Medicine indicates that for women who have newly diagnosed cancer in one breast, MRI can find tumors in the other breast that mammograms miss.
- The ability of MRI to detect breast cancer is directly related to high-quality imaging, particularly the signal-to-noise-ratio, as well as spatial resolution of the MRI image.
- Residents of western North Carolina do not have local access to dedicated breast MRI services.
- Failure to allow the implementation of this technology in HSA I may increase long-term health costs, because existing modalities are less likely to detect cancer compared to MRI.
- Hope already has resources in place, including stereotactic breast biopsy, to effectively provide dedicated breast MRI services.

CA Cancer J Clin 2007; 57:75-89

American Cancer Society Guidelines for Breast Screening with MRI as an Adjunct to Mammography

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ABSTRACT

New evidence on breast Magnetic Resonance Imaging (MRI) screening has become available since the American Cancer Society (ACS) last issued guidelines for the early detection of breast cancer in 2003. A guideline panel has reviewed this evidence and developed new recommendations for women at different defined levels of risk. Screening MRI is recommended for women with an approximately 20 25% or greater lifetime risk of breast cancer, including women with a strong family history of breast or ovarian cancer and women who were treated for Hodgkin disease. There are several risk subgroups for which the available data are insufficient to recommend for or against screening, including women with a personal history of breast cancer, carcinoma in situ, atypical hyperplasia, and extremely dense breasts on mammography. Diagnostic uses of MRI were not considered to be within the scope of this review.

INTRODUCTION

Mammography has been proven to detect breast cancer at an early stage and, when followed up with appropriate diagnosis and treatment, to reduce mortality from breast cancer. For women at increased risk of breast cancer, other screening technologies also may contribute to the earlier detection of breast cancer, particularly in women under the age of 40 years for whom mammography is less sensitive. The American Cancer Society (ACS) guideline for the early detection of breast cancer, last updated in 2003, stated that women at increased risk of breast cancer might benefit from additional screening strategies beyond those offered to women at average risk, such as earlier initiation of screening, shorter screening intervals, or the addition of screening modalities (such as breast ultrasound or magnetic resonance imaging [MRI]) other than mammography and physical examination. However, the evidence available at the time was insufficient to justify recommendations for any of these screening approaches. The ACS recommended that decisions about screening options for women at significantly increased risk of breast cancer be based on shared decision making after a review of potential benefits, limitations, and harms of different screening strategies and the degree of uncertainty about each.[1]

Although there still are limitations in the available evidence, additional published studies have become available since the last update, particularly regarding use of breast MRI. The ACS guideline panel has sought to provide additional guidance to women and their health care providers based on these new data.

GUIDELINE DEVELOPMENT

The ACS convened an expert panel to review the existing early detection guideline for women at increased risk and for MRI screening based on evidence that has accumulated since the last revision in 2002 to 2003. Literature related to breast MRI screening published between September 2002 and July 2006 was identified using MEDLINE (National Library of Medicine), bibliographies of identified articles, and unpublished manuscripts. Expert panel members reviewed and discussed data during a series of conference calls and a working meeting in August, 2006. When evidence was insufficient or lacking, the final recommendations incorporated the

expert opinions of the panel members. The ACS Breast Cancer Advisory Group members and the National Board of Directors discussed and voted to approve the recommendations.

SUMMARY OF RECOMMENDATIONS

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Table 1 summarizes the ACS recommendations for breast MRI screening.

View this table: TABLE 1 Recommendations for Breast MRI Screening as an Adjunct to Mammography
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BACKGROUND

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MRI

MRI utilizes magnetic fields to produce detailed cross-sectional images of tissue structures, providing very good soft tissue contrast. Contrast between tissues in the breast (fat, glandular tissue, lesions, etc.) depends on the mobility and magnetic environment of the hydrogen atoms in water and fat that contribute to the measured signal that determines the brightness of tissues in the image. In the breast, this results in images showing predominantly parenchyma and fat, and lesions, if they are present. A paramagnetic small molecular gadolinium-based contrast agent is injected intravenously to provide reliable detection of cancers and other lesions. Thus, contrast enhanced MRI has been shown to have a high sensitivity for detecting breast cancer in high-risk asymptomatic and symptomatic women, although reports of specificity have been more variable.[2-8] This high signal from enhancing lesions can be difficult to separate from fat, leading to the use of subtraction images or fat suppression, or both, to assess disease. Because parenchymal tissue also enhances, but generally more slowly than malignant lesions, and also because contrast can wash out rapidly from some tumors, it is important to look at images at an early time point after contrast injection (typically 1 to 3 minutes). MRI examinations may involve examining images at one time point or, more often, will collect a preinjection image with sequential sets of images after contrast injection (dynamic contrast-enhanced [DCE]-MRI). Both the appearance of lesions and, where available, the uptake and washout pattern can be used to identify malignant disease and discriminate it from benign conditions.

These techniques, which have been widely employed for assessing symptomatic disease, have recently been shown to provide good sensitivity as a screening tool for breast cancer in women at increased risk based on family history.[9-14] The approach requires appropriate techniques and equipment, together with experienced staff. Higher quality images are produced by dedicated breast MRI coils, rather than body, chest, or abdominal coils.

IDENTIFICATION OF WOMEN WITH A HIGH RISK OF BREAST CANCER

Three approaches are available for identifying women with a high risk of breast cancer: family history assessment, genetic testing, and review of clinical history. All contribute to identifying women who are candidates for breast MRI screening.

Family History

Although a high proportion of women in the general population have at least one relative with breast cancer, for the majority of these women, this "family history" either does not increase risk at all (ie, the cancer was sporadic) or is associated with, at most, a doubling of lifetime risk (due to either shared environmental risk factors or an inherited gene of low penetrance). Only 1% to 2% of women have a family history suggestive of the inheritance of an autosomal dominant, high-penetrance gene conferring up to an 80% lifetime risk of breast cancer. In some families, there is also a high risk of ovarian cancer. Features of the family history which suggest the cancers may be due to such a high-penetrance gene include 2 or more close (generally first- or second-degree) relatives with breast or ovarian cancer; breast cancer occurring before age 50 years (premenopausal) in a close relative; a family history of both breast and ovarian cancer; one or more relatives with 2 cancers (breast and ovarian cancer or 2 independent breast cancers); and male relatives with breast cancer.[15–18]

Two breast/ovarian cancer susceptibility genes, *BRCA1* and *BRCA2*, have been identified.[19,20] Inherited mutations in these genes can be found in approximately 50% of families in which an inherited risk is strongly suspected based on the frequency and age of onset of breast cancer cases, and in most families in which there is a much higher than expected incidence of both breast and ovarian cancer.

Several models can assist clinicians to estimate breast cancer risk or the likelihood that a *BRCA* mutation is present (Online Supplemental Material). The Gail, Claus, and Tyrer-Cusick models estimate breast cancer risk based on family history, sometimes in combination with other risk factors, such as reproductive history or prior breast biopsies.[16,21–23] Although risk prediction is generally similar for the different models, an individual woman's risk estimate may vary with different models.[21,24,25]

Two decision models have been developed to estimate the likelihood that a *BRCA* mutation is present, BRCAPRO[18,26] and the Breast and Ovarian Analysis of Disease Incidence and Carrier Estimation Algorithm (BOADICEA)[27]; the BOADICEA model also provides estimates of breast cancer risk (Online Supplemental Material).

Genetic Testing

The prevalence of *BRCA* mutations is estimated to be between 1/500 and 1/1,000 in the general population[28]; however, in women of Jewish ethnicity, the prevalence is 1/50.[29,30] Women with cancer-predisposing mutations in either *BRCA1* or *BRCA2* have an increased risk of both breast and ovarian cancer. From population-based studies, women with *BRCA1* mutations are estimated to have a 65% risk by age 70 years for developing breast cancer (95% confidence interval [CI], 44% to 78%); the corresponding risk for *BRCA2* mutations is 45% (95% CI, 31% to 56%).[31] Risks estimated from cancer-prone families seen in referral centers are higher, with limit of risk in the 85% to 90% range.[31] These mutations follow an autosomal dominant pattern of transmission, which means that the sister, mother, or daughter of a woman with a *BRCA* mutation has a 50% chance of having the same mutation.

The benefits and risks of genetic testing are beyond the scope of this article, but are reviewed in the American Society of Clinical Oncology policy statement update on genetic testing for cancer susceptibility.[32] Genetic testing for a *BRCA1* or *BRCA2* mutation is generally offered to adult members of families with a known *BRCA* mutation, or to women with at least a 10% likelihood of carrying such a mutation, based on either validated family history criteria or one of the above-mentioned models. If a woman from a family in which a *BRCA* mutation has been previously identified does not have that mutation, one can generally safely conclude that her breast cancer risk is no

higher than it would have been if she did not have a family history of breast cancer. However, in a high-risk family without a known mutation, failure to find a mutation in a particular member does not reduce her risk estimate.

A high risk of breast cancer also occurs with mutations in the *TP53* gene (Li-Fraumeni syndrome) and the *PTEN* gene (Cowden and Bannayan-Riley-Ruvalcaba syndromes).[33] Accurate prevalence figures are not available, but these conditions appear to be very rare.[34,35]

Clinical Indicators of Risk

Some clinical factors are associated with substantial breast cancer risk. Among women with Hodgkin disease, increased breast cancer risk has been consistently and significantly associated with mantle field radiation treatment. In several studies of women treated between 1955 and 1995, risk was inversely related to age at treatment in patients diagnosed between the ages of 10 to 30 years, with only slight or no increased risk when diagnosis was before age 10 years or after age 30 years.[36-41] Risk following treatment with radiation and chemotherapy was half that of treatment with radiation alone in two studies,[39,42] which may reflect the effect of chemotherapy on earlier onset of menopause; risk was equivalent in a third study.[43] Risk of breast cancer significantly increased 15 to 30 years after radiation therapy.[41] More recently, treatment approaches have used lower doses of radiation and limited-field radiotherapy. In one study, which compared patients who received radiation therapy in 1966 to 1974 and 1975 to 1985, treatment in the later timeframe was not related to increased risk of breast cancer after a median follow up of 13 years, whereas patients treated between 1966 and 1974 were at increased risk, suggesting that Hodgkin disease survivors treated with current approaches will not face substantially increased breast cancer risk.[44]

Lobular carcinoma in situ (LCIS) and atypical lobular hyperplasia (ALH), together described as lobular neoplasia, are associated with substantially increased risk of subsequent breast cancer, with lifetime risk estimates ranging from 10% to 20%.[45] This equates to a continuous risk of about 0.5% to 1.0% per year. The invasive cancers may be ipsilateral or contralateral, are usually invasive lobular cancers, and more than 50% of these diagnoses occur more than 15 years after the original diagnosis of LCIS. Similar findings have been reported by Fisher et al,[46] describing a 12-year update of 180 women with LCIS who were treated with local excision alone and followed by the National Surgical Adjuvant Breast Project (NSABP), as well as Li et al, who described the risk of invasive breast cancer among 4,490 LCIS patients using Surveillance, Epidemiology, and End Results (SEER) data between 1988 to 2001.[47]

Atypical ductal hyperplasia (ADH) is part of the continuum of ductal proliferative breast diseases ranging from usual ductal hyperplasia to ductal carcinoma in situ (DCIS). The literature review by Arpino et al[45] suggests a 4- to 5-fold increased risk of invasive breast cancer (compared with a 6- to 10-fold risk with LCIS) at a median follow up of 17 years, which is doubled if the woman has an associated family history of breast cancer. It is unclear, however, what percentage of the women with this family history and ADH are at this significantly increased risk because they are carriers of a *BRCA1* or 2 gene mutation.

Mammographic density has been shown to be a strong independent risk factor for the development of breast cancer.[48-51] In several studies, women with the most breast density were found to have a 4- to 6-fold increased risk of breast cancer, compared with women with the least dense breasts.[52-56] For example, women with 75% or higher mammographic density had a more than five-fold increased risk of breast cancer, compared with women with less than 1% density.[57] In addition, it has been shown that malignant tumors of the breast are more likely to arise in the areas of greatest mammographic density, compared with the more fatty areas of the breast.[58]

The absolute risk of contralateral breast cancer in women with a personal history of breast cancer is estimated to be 0.5% to 1% per year, or 5% to 10% during the 10 years following diagnosis, significantly higher than that of the general population.[59] Hormone therapy and or chemotherapy for the primary cancer is likely to subsequently lower the risk of contralateral breast cancer.

EVIDENCE AND RATIONALE

Evidence of Efficacy from MRI Screening Studies

In the mid to late 1990s, at least 6 prospective, nonrandomized studies were initiated in The Netherlands, the United Kingdom (UK), Canada, Germany, the United States (US), and Italy to determine the benefit of adding annual MRI to (film) mammography for women at increased risk of breast cancer. Some of the studies included ultrasound and/or clinical breast examination, as well. Despite substantial differences in patient population (age, risk, etc.) and MRI technique, all reported significantly higher sensitivity for MRI compared with mammography (or any of the other modalities). All studies that included more than one round of screening reported interval cancer rates below 10%. Participants in each of these 6 studies had either a documented *BRCA1* or *BRCA2* mutation or a very strong family history of breast cancer. Some of the studies included women with a prior personal history of breast cancer.

Kriege et al screened 1,909 unaffected women aged 25 to 70 years with an estimated 15% or higher lifetime risk of breast cancer (19% proven to have a *BRCA* mutation) at 6 centers across The Netherlands.[9] After a median of 3 rounds of screening, 50 breast cancers (44 invasive) were diagnosed. Eighty percent of the invasive cancers were detected by MRI, compared with 33% by mammography. However, mammography outperformed MRI for detecting DCIS. Of the invasive cancers, 43% were 1 cm or smaller in diameter, and 33% had spread to axillary lymph nodes. The specificity of MRI was 90%, compared with 95% for mammography.

Leach et al screened 649 unaffected women aged 35 to 49 years who had at least a 25% lifetime risk of breast cancer (19% proven to have a *BRCA* mutation) at 22 centers in the UK.[11] After a median of 3 rounds of screening, 35 cancers (29 invasive) were diagnosed. Sensitivity of MRI was 77%, compared with 40% for mammography, with specificities of 81% and 93%, respectively. MRI was most sensitive and mammography least sensitive for women with *BRCA1* mutations. Forty-five percent of the cancers were 1 cm or less in size, and 14% had spread to axillary lymph nodes. There were two interval cancers.

Warner et al screened 236 women aged 25 to 65 years with a *BRCA* mutation at a single center in Toronto for up to 3 years and detected 22 cancers (16 invasive).[14] Sensitivity of MRI was 77%, compared with 36% for mammography, with 50% of the cancers 1 cm or smaller, and 13% were node positive. There was one interval cancer. Specificity was 95% for MRI and 99.8% for mammography.

Kuhl et al screened 529 women aged 30 years and older with a lifetime breast cancer risk of at least 20% at a single center in Bonn for a mean of 5 years.[10] They detected 43 cancers (34 invasive), with 1 interval cancer. The sensitivity of MRI was 91%, compared with 33% for mammography. The node positive rate was 16%. Specificity of both MRI and mammography was 97%.

The International Breast MRI Consortium screened 390 women aged 25 years and older with more than a 25% lifetime risk of breast cancer at 13 centers (predominantly in the US) on a single occasion.[12] Four cancers were found by MRI, and only one of these by mammography. However, because the patients were not followed after screening, the false-negative rate could not be determined. MRI specificity was 95%, compared with 98% for mammography.

In a study in Italy with 9 participating centers, Sardanelli et al screened 278 women aged 25 years and older; 27% carried a *BRCA* mutation or had a first-degree relative with a *BRCA* mutation.[13] After a median of 1.4 rounds of screening, 18 cancers (14 invasive) were found. MRI sensitivity was 94%, compared with 59% for mammography, 65% for ultrasound, and 50% for clinical breast examination. MRI specificity was 99%.

Overall, studies have found high sensitivity for MRI, ranging from 71% to 100% versus 16% to 40% for mammography in these high-risk populations. Three studies included ultrasound, which had sensitivity similar to mammography. The Canadian, Dutch, and UK studies[9,11,14] reported similar sensitivity (71% to 77%) within CIs for MRI, although the single-center study from Germany10 reported a higher sensitivity, which may reflect the concentration of radiological practice and higher patient volume per radiologist at a single center. There is evidence of a learning curve for radiologists conducting MRI breast screening, with the number of lesions investigated falling with experience.[60] The three multicenter studies reflect the likely initial effectiveness of this modality in a population context, and it is expected that, with training and advances in technology, sensitivity will increase further.

Table 2 provides a summary of these six screening studies.

View this table: TABLE 2 Published Breast MRI Screening Study Results
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Most of the available data are based on screening women at high risk due to family history and/or genetic mutations. More recently, smaller studies have provided information on the potential benefit of MRI screening for women with clinical factors that put them at increased risk. Preliminary data were obtained from one retrospective study, in which Port et al[61] reviewed the screening results of 252 women with biopsy-confirmed LCIS and 126 women with atypical hyperplasia (either ductal or lobular), of whom half were screened with annual mammography and biennial clinical exams and half were also screened with MRI. The women who were screened with MRI were younger and more likely to have a strong family history. MRI screening offered a small advantage to patients with LCIS, but not atypical hyperplasia, and also resulted in increased biopsies: 6 cancers were detected by MRI in 5 women with LCIS (4% of patients undergoing MRI), and none were detected in women with atypical hyperplasia. Biopsies were recommended for 25% of MRI screened patients; 13% of biopsies had a cancer detected. All of the cancers in women screened with MRI were Stage 0 to I, whereas all of the cancers in women who were not screened with MRI were Stage I to II. Cancer was detected on the first MRI in 4 of 5 patients. The sensitivity of MRI was 75%, the specificity was 92%, and the positive predictive value was 13%.

Technological Limitations and Potential Harms Associated with MRI Screening

Although the efficacy of breast MRI has been demonstrated, it does not achieve perfect sensitivity or specificity in women undergoing screening, and as such, the issue of adverse consequences for women who do, but especially those who do not, have breast cancer is important to address. As with mammography and other screening tests, false negatives after MRI screening can be attributed to inherent technological limitations of MRI, patient characteristics, quality assurance failures, and human error; false positives also can be attributed to these factors, as well as heightened medical-legal concerns over the consequence of missed cancers. A patient's desire for definitive findings in the presence of a low-suspicion lesion may also contribute to a higher rate of benign biopsies. The consequences of all these factors include missed cancers, with potentially worse prognosis, as well as anxiety and potential harms associated with interventions for benign lesions.

The specificity of MRI is significantly lower than that of mammography in all studies to date, resulting in more recalls and biopsies. Call-back rates for additional imaging ranged from 8% to 17% in the MRI screening studies, and biopsy rates ranged from 3% to 15%.[9,14] However, several researchers have reported that recall rates decreased in subsequent rounds of screening: prevalence screens had the highest false-positive rates, which subsequently dropped to less than 10%.[9,62,63] Most call backs can be resolved without biopsy. The call-back and biopsy rates of MRI are higher than for mammography in high-risk populations; while the increased sensitivity of MRI leads to a higher call-back rate, it also leads to a higher number of cancers detected. The proportion of biopsies that are

cancerous (positive predictive value) is 20% to 40%.[9, 14] Since false-positive results appear to be common, more data are needed on factors associated with lower specificity rates.

Table 3 compares the likelihood of detection and follow-up tests for women who underwent screening MRI and mammography in two screening studies (Dutch and UK). The study populations differed, with the Dutch study having a wider age group and lower risk category, compared with the UK study.[9,11] This affected both the prevalence of cancer and the pick-up rate by modality in the two studies. These results, drawn from two trials, demonstrate the relatively high recall rate in the high-risk population, as well as the fact that MRI is a relatively new technique. Despite the high number of recalls, because of the high cancer rate, the rate of benign surgical biopsy in the UK study per cancer detected was similar to that experienced in the population-based national breast screening service. Recalls will inevitably lead to additional investigations, many of which will not demonstrate that cancer is present.

View this table: [in this window] [in a new window] TABLE 3 Rates of Detection and Follow-up Tests for Screening MRI Compared with Mammography

Given the high rate of cancer combined with the risk of false-positive scans in a high-risk population undergoing MRI-based screening, the psychological health of these women merits study. In a subgroup of 611 women in the UK study, 89% reported that they definitely intended to return for further screening, and only 1% definitely intended not to return. However, 4% found breast MRI "extremely distressing," and 47% reported still having intrusive thoughts about the examination 6 weeks afterward.[64]

In a sample of 357 women from the Dutch study, psychological distress remained within normal limits throughout screening for the group as a whole. However, elevated breast cancer-specific distress related to screening was found in excessive (at least once per week) breast self-examiners, risk overestimators, and women closely involved in the breast cancer case of a sister. At least 35% of the total sample belonged to one of these subgroups. It was recommended that patients in one of these vulnerable subgroups be approached for additional psychological support.[65]

In a small sample of women from the Toronto study followed over a course of 2 years, there was no evidence of any effect on global anxiety, depression, or breast cancer-related anxiety.[66] In another sample of 57 women, almost 50% had elevated baseline general and or breast cancer-specific anxiety, but in 77% of cases this was attributed by the patients to life events, including relatives with cancer. A nonsignificant increase in general anxiety and breast cancer-related anxiety, compared with baseline, was found in the subset of women recalled for further imaging or biopsies.[67] Follow-up time is still insufficient to determine whether anxiety scores return to baseline once the work up has been completed.

There is a special responsibility to alert patients to this technology, with its potential strengths and harms, and to be encouraging, while allowing for shared decision making. The interplay between risks, benefits, limitations, and harms is complicated by the fact that individual women likely will weigh these differently depending on their age, values, perception of risk, and their understanding of the issues. Steps should be taken to reduce anxiety associated with screening and the waiting time to diagnosis, and conscientious efforts should be made to inform women about the likelihood of both false-negative and false-positive findings. How information is conveyed to the patient greatly influences the patient's response: it is important that providers not convey an undue sense of anxiety about a positive MRI finding. While the high rate of biopsies and further investigations is acceptable in women with a high risk of breast cancer, the number of such investigations in women at lower risk will be much higher than would be appropriate, leading to the need to counsel women in lower risk categories that MRI screening is not advisable and

that the harms are believed to outweigh the benefits. Such advice needs to be based on considerations of family history, genetic mutation status, other risk factors, age, and mammographic breast density.

There are substantial concerns about costs of and limited access to high-quality MRI breast screening services for women with familial risk. In addition, MRI-guided biopsies are not widely available. With many communities not providing MRI screening and with MRI-guided biopsies not widely available, it is recognized that these recommendations may generate concerns in high-risk women who may have limited access to this technology.

The ability of MRI to detect breast cancer (both invasive and in situ disease) is directly related to high-quality imaging, particularly the signal-to-noise ratio, as well as spatial resolution of the MR image. In order to detect early breast cancer (ie, small invasive cancers, as well as DCIS), simultaneous imaging of both breasts with high spatial resolution is favored. High spatial resolution imaging should be performed with a breast coil on a high field magnet with thin slices and high matrix (approximately 1 mm in-plane resolution). These technical parameters are considered to be the minimal requirements to perform an adequate breast MRI study. The ability to perform MRI-guided biopsy is absolutely essential to offering screening MRI, as many cancers (particularly early cancers) will be identified only on MRI. The American College of Radiology (ACR) is currently developing an accreditation process for performing breast MRI, and, in addition to the performance of high spatial resolution images, the ability to perform MRI intervention (ie, needle localization and/or biopsy) will be essential in order to obtain accreditation by this group. Accreditation will be voluntary and not mandatory. This guideline will likely be available in 2007.

There is a learning curve with respect to interpretation for radiologists. Published trial sites that experience a high volume of cases are experienced, but community practice groups have reported call-back rates over 50% in the majority of the studies that are interpreted. Experience and familiarity with patterns of enhancement, normal and possibly abnormal, are thought to decrease recall rates and increase positive biopsy rates. The ACR accreditation process will stipulate a minimum number of exams that must be read for training purposes and a minimum number for ongoing accreditation. Sites performing breast MRI are encouraged to audit their call-back rates, biopsy rates, and positive biopsy rates.

Cost-effectiveness

Only limited data are available on the cost-effectiveness of breast MRI screening. One recent study modeled cost-effectiveness for adding MRI to mammography screening for women of different age groups who carry a *BRCA1* or *BRCA2* mutation.[68] The authors concluded that the cost per quality-adjusted life year (QALY) saved for annual MRI plus film mammography, compared with annual film mammography alone, varied by age and was more favorable in carriers of a mutation in *BRCA1* than *BRCA2* because *BRCA1* mutations confer higher cancer risk, and higher risk of more aggressive cancers, than *BRCA2* mutations.[31] Estimated cost per QALY for women aged 35 to 54 years was $55,420 for women with a *BRCA1* mutation and $130,695 for women with a *BRCA2* mutation. Cost-effectiveness was increased when the sensitivity of mammography was lower, such as in women with very dense breasts on mammography: estimated costs per QALY were $41,183 for women with a *BRCA1* mutation and $98,454 for women with a *BRCA2* mutation with dense breast tissue. The most important determinants of cost-effectiveness were breast cancer risk, mammography sensitivity, MRI cost, and quality of life gains from MRI.

An evaluation of the cost-effectiveness of the UK study[69] has determined that the incremental cost per cancer detected for women at approximately 50% risk of carrying a *BRCA* gene mutation was $50,911 for MRI combined with mammography over mammography alone. For known mutation carriers, the incremental cost per cancer detected decreased to $27,544 for MRI combined with mammography, compared with mammography alone. Analysis supporting the introduction of targeted MRI screening in the UK for high-risk women70 identified the incremental cost of combined screening per QALY in 40- to 49-year-old women as $14,005 for a *BRCA1* carrier with a 31% 10-year riskthe group in which MRI screening is seen to be most effective; $53,320 for women with a 12% 10-year risk; and $96,379 for women with a 6% 10-year risk. For the 30- to 39-year-old age range, the incremental costs per QALY are $24,275 for a *BRCA1* carrier with an 11% 10-year risk and $70,054 for a women

with a 5% 10-year risk. Based on these estimates, which are based on costs within the UK National Health Service, MRI screening will be offered to women at familial risk aged 30 to 39 years at a 10-year risk greater than 8%, and to women at familial risk aged 40 to 49 years at a 10-year risk greater than 20%, or greater than 12% when mammography has shown a dense breast pattern.

Evidence Supporting Benefit of MRI Screening Among Women in Different Risk Categories

The guideline recommendations were based on consideration of (1) estimates of level of risk for women in various categories and (2) the extent to which risk groups have been included in MRI studies, or to which subgroup-specific evidence is available. Because of the high false-positive rate of MRI screening, and because women at higher risk of breast cancer are much more likely to benefit than women at lower risk, screening should be recommended only to women who have a high prior probability of breast cancer. There is growing evidence that breast cancer in women with specific mutations may have biological and histological features that differ from sporadic cancers. This may result in observed variations in the sensitivity of MRI relative to mammography in detecting cancer in women with a *BRCA* mutation and those at high familial risk, but without mutations in these genes.[11]

Women at Increased Risk Based on Family History

The threshold for defining a woman as having significantly elevated risk of breast cancer is based on expert opinion. Any woman with a *BRCA1* or *BRCA2* mutation should be considered at high risk. The panel has not restricted its recommendations only to women with *BRCA* mutations because *BRCA* testing is not always available or informative, and other risk indicators identify additional subsets of women with increased breast cancer risk. If mutation testing is not available, has been done and is noninformative, or if a woman chooses not to undergo testing, pedigree characteristics suggesting high risk may be considered. Very careful family history analysis is required, using tools such as BRCAPRO.[18,26] Risk assessment is likely to offer the greatest potential benefit for women under the age of 40 years. Table 4 provides examples of women with a family history indicative of moderate and high risk. The online supplemental material provides guidance for accessing and using risk assessment models.

View this table: TABLE 4 Breast Cancer Risks for Hypothetical Patients, Based on 3 Risk Models
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Women at Increased Risk Based on Clinical Factors

Additional factors that increase the risk of breast cancer, and thus may warrant earlier or more frequent screening, include previous treatment with chest irradiation (eg, for Hodgkin disease), a personal history of LCIS or ADH, mammographically dense breasts, and a personal history of breast cancer, as discussed above. There are little data to assess the benefit of MRI screening in women with these risk factors. Women at increased risk or who are concerned about their risk may find it helpful to have their provider clarify the bases for MRI screening recommendations, as well as areas of uncertainty. For some women, mammography may be as effective as for women at average risk, and MRI screening may have little added benefit. In contrast, mammography is less effective in women with very dense breasts, and MRI screening may offer added benefit.

Women who have received radiation treatment to the chest, such as for Hodgkin disease, compose a well-defined group that is at high risk. Although evidence of the efficacy of MRI screening in this group is lacking, it is expected that MRI screening might offer similar benefit as for women with a strong family history, particularly at younger ages and within 30 years of treatment. Because of the high risk of secondary breast cancer in this group, MRI screening is recommended based on expert consensus opinion.

While lifetime risk of breast cancer for women diagnosed with LCIS may exceed 20%, the risk of invasive breast cancer is continuous and only moderate for risk in the 12 years following local excision.[46] Only one MRI screening

study has included a select group of women with LCIS,[61] which showed a small benefit over mammography alone in detecting cancer. This benefit was not seen in patients with atypical hyperplasia. MRI use should be decided on a case-by-case basis, based on factors such as age, family history, characteristics of the biopsy sample, breast density, and patient preference.

Although there have been several trials reported looking at the accuracy and positive predictive value of MRI and mammography in women with high breast density, all of these trials have been conducted in women with known or highly-suspected malignancies within the breast.[71-74] To this point, there has been no Phase III randomized trial reported that has shown a reduction in either mortality or in the size of diagnosed breast cancer when comparing breast MRI with mammography in women with high mammographic density.

Scant data are available for MRI screening of women with a personal history of breast cancer. In one study, MRI detected more cancers in women who had both a personal history and a family history, compared with women at high risk based on family history alone.[75] While women with a previous diagnosis of breast cancer are at increased risk of a second diagnosis, the ACS panel concluded that the estimated absolute lifetime risk of 10% does not justify a recommendation for MRI screening at the present time.

Limitations of Evidence from MRI Studies and Research Needs

Assiduous attempts were made to base recommendations on solid evidence. However, outcome data from screening MRI studies are not sufficient to form a solid basis for many of the recommendations. It was therefore necessary to rely on available inferential evidence and expert opinion to provide the guidance needed for patients and their health care providers.

Although the literature shows very good evidence for greater sensitivity of MRI than mammography and good evidence for a stage shift toward earlier, more favorable tumor stages by MRI in defined groups of women at increased risk, there are still no data on recurrence or survival rates, and therefore, lead-time bias is still a concern. Further, a large randomized, mortality endpoint study is unlikely to take place, and it will be necessary in the foreseeable future to rely on evidence of stage of disease and types of cancers. In the absence of randomized trials, recurrence and survival data will come from observational study designs.

The age at which screening should be initiated for women at high risk is not well established. The argument for early screening is based on the cumulative risk of breast cancer in women with *BRCA1* mutations and a strong family history of early breast cancer, which is estimated to be 3% by age 30 years and 19% by age 40 years.[76] Population-based data also indicate that risk for early breast cancer is increased by a family history of early breast cancer.[16] Based on these observations, some experts have suggested that breast cancer screening begin 5 to 10 years before the earliest previous breast cancer in the family. In 1997, an expert panel suggested that screening be initiated at some time between the ages of 25 and 35 years for women with a *BRCA1* or *BRCA2* mutation.[77] Because these recommendations were based on limited observational data, the decision regarding when to initiate screening should be based on shared decision making, taking into consideration individual circumstances and preferences. No data are available related to the effectiveness of screening women beyond age 69 years with MRI and mammography versus mammography alone; most of the current data are based on screening in younger women, and thus, similar investigations are needed in older age cohorts. For most women at high risk, screening with MRI and mammography should begin at age 30 years and continue for as long as a woman is in good health.[1]

Most of the available data are based on annual MRI screening; there is a lack of evidence regarding shorter or longer screening intervals. Further, while good data are available for the first screening exam (ie, the "prevalent screen"), considerably less data are available from subsequent screening exams (ie, "incidence screens"), and the available data include relatively short follow-up times. Most studies of annual MRI have shown few interval cancers, certainly fewer than with mammography. Given the probably shorter duration of the detectable preclinical phase, or sojourn time, in women with *BRCA* mutations, MRI has demonstrated superiority to mammography in this

regard. Therefore, to the best of our knowledge, MRI should be performed annually. However, in view of data suggesting that tumor doubling time in women with an inherited risk decreases with age,78 it is conceivable that older women can safely be screened less frequently than younger women. The available evidence is limited, and additional research regarding optimal screening interval by age and risk status is needed.

Some experts recommend staggering MRI screening and mammography screening every 6 months. The potential advantage of this approach is that it may reduce the rate of interval cancers. Other experts recommend MRI and mammography at the same time or within a short time period. This approach allows for the results of both screening tests to be interpreted together and reported to the patient at the same time. All of the clinical trials screened participants with both MRI and mammography at the same time. There is no evidence to support one approach over the other. For the majority of women at high risk, it is critical that MRI screening be provided in addition to, not instead of, mammography, as the sensitivity and cancer yield of MRI and mammography combined is greater than for MRI alone. However, where there is a concern about raised radiation sensitivity, it may be advisable to employ MRI alone despite the overall lower sensitivity.

In order to pursue answers to some of the unresolved questions related to the use of MRI and mammography to screen women at increased risk, it is important to develop creative strategies related to data gathering and study design. Multicenter studies can result in greater efficiency in accumulating sufficiently large enough data sets in this subgroup of women. Conventional study designs with randomization may prove difficult given the potential advantage of adding MRI to mammography in higher-risk groups, and thus, design strategies that utilize surrogate markers and historic controls may prove both more practical and feasible. To move forward, we encourage the development of a simple, common data collection protocol to capture information from the growing number of centers that offer MRI and formal systems to collect outcome data. Because many insurers presently cover MRI screening for high-risk women, it may be economical to do prospective surveillance studies since screening costs are covered by third parties. A common surveillance protocol could permit pooling of data, much like presently is done within the framework of the National Cancer Institute's Breast Cancer Surveillance Consortium, a collaborative network of seven mammography registries in the United States with linkages to tumor and or pathology registries that was organized to study the delivery and quality of breast cancer screening and related patient outcomes in the United States.[79] We also encourage seeking opportunities for broad international research collaboration on study questions of common interest.

Several further clinical trials of screening women at increased risk of breast cancer are underway, including an international study of MRI and ultrasound in conjunction with the International Breast MRI Consortium and Cancer Genetics Network, and the American College of Radiology Imaging Network (ACRIN) 666 screening trial of mammography compared with ultrasound. An amendment to the ACRIN trial, 6666, will screen patients with one round of MRI.

CONCLUSION

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Often no available screening modality is uniquely ideal. For breast MRI, there is an increasing body of observational data showing that screening can identify cancer in patients of specific risk groups, ie, high-risk patients facing a lifetime risk of ~20–25% or greater related to family history as estimated by one or more of the different risk models. We have specified a range of risk because estimates from the risk models vary and because each of the risk models is imperfect. Furthermore, these models likely will continue to be refined over time; therefore, these risk estimates for different family history profiles are likely to change. Thus, when estimating patient risk it is important to always be certain that the most current model is being used. In addition to family

history, clinical factors as described earlier may be a relevant factor in individualized decisions about MRI screening when family history alone does not predict a risk of approximately 20–25%.

Several studies have demonstrated the ability of MRI screening to detect cancer with early-stage tumors that are associated with better outcomes. While survival or mortality data are not available, MRI has higher sensitivity and finds smaller tumors, compared with mammography, and the types of cancers found with MRI are the types that contribute to reduced mortality. It is reasonable to extrapolate that detection of noninvasive (DCIS) and small invasive cancers will lead to mortality benefit.

The guideline recommendations for MRI screening as an adjunct to mammography for women at increased risk of breast cancer take into account the available evidence on efficacy and effectiveness of MRI screening, estimates of level of risk for women in various categories based on both family history and clinical factors, and expert consensus opinion where evidence for certain risk groups is lacking. All of these groups of women should be offered clinical trials of MRI screening, if available. Women should be informed about the benefits, limitations, and potential harms of MRI screening, including the likelihood of false-positive findings. Recommendations are conditional on an acceptable level of quality of MRI screening, which should be performed by experienced providers in facilities that provide MRI-guided biopsy for the follow up of any suspicious results.

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Technology and Equipment Committee Meeting

August 29, 2007

MRI MATERIAL

Material Related to

MRI Comment – 4: HOPE, A Women's Cancer Center

Asheville PH
July 13 2007

Hope
A Women's Cancer Center

SHCC Public Hearing Presentation Comments
Adjusted Need Determination – 2008 State Medical Facilities Plan
Dedicated Breast MRI Scanner in HSA I
July 13, 2007

Good afternoon, my name is Mariann Smith. I am the Administrator at Hope – A Women's Cancer Center in Asheville. I am here today to speak on behalf of our petition for an adjusted need determination for one dedicated breast MRI scanner in Buncombe County to serve residents in HSA I.

Approval of this petition will enable any eligible applicant the opportunity to submit competitive Certificate of Need applications proposing the best plan for addition of a dedicated breast MRI scanner in Buncombe County.

Breast cancer is the most common cancer among women. The chance of developing invasive breast cancer at some time in a woman's life is about 1 in 7. For breast cancer, early detection saves lives. For example, almost 98 percent of women who are diagnosed with breast cancer in the earliest stage survive the disease, whereas only 26 percent survive if the disease is diagnosed in the most advanced stage. The opportunity for disease control and for reducing the number of cancer deaths rests with prevention and early detection so that treatment of the disease can be effective. This is the foundation of our petition for a dedicated breast MRI scanner in Buncombe County.

Hope is aware that the 2006 State Medical Facilities Plan included an adjusted need determination for a dedicated and specialized breast MRI scanner. This adjusted need determination was the result of a petition submitted by Novant Health. This petition was based on American Cancer Guidelines that were released in 2003 stating women might benefit from additional screening strategies beyond those offered to women at average risk. However, new evidence on breast MRI screening has become available since the American

Cancer Society last issued guidelines in 2003. A guideline panel has reviewed this evidence and developed new recommendations for women at different levels of risk.

According to the American Cancer Society, women with a genetic predisposition to breast cancer, and/or those with a family history of the disease, should undergo annual MRI screening along with routine mammograms.
Specific guidelines were released in March of 2007 identifying the women who should have a breast MRI scan. These guidelines include:

- Those who are BRCA mutation carriers;
- Women with first-degree relatives who are BRCA mutation carriers;
- Women with a 20% to 25% lifetime risk of breast cancer based on family history;
- Women who had radiation treatment to the chest between the ages of 10 and 30; and
- Women with specific genetic syndromes.

The guideline states that, for high-risk women, screening with MRI and mammography should begin at age 30. These new guidelines demonstrate that a much larger population can benefit from breast MRI screening compared to the 2003 guidelines. Based on the 2007 American Cancer Society guidelines, geography and demographic data, a dedicated breast MRI scanner is of great need for residents of Buncombe County and HSA I.

I previously mentioned that one guideline for identifying women who should have a breast MRI scan are those who are BRCA mutation carriers. The prevalence of BRCA mutations is estimated to be between 1/500 and 1/100 in the general population. This equates to approximately 445 Buncombe County residents and over 2,700 people in HSA I who could benefit from a breast MRI scanner.

The guidelines also state that women with a 20% to 25% lifetime risk of breast cancer based on family history should have a breast MRI. According to the American Cancer Society, 2% of women have a family history suggestive of breast cancer inheritance. While 2% may sound nominal, this equates to as many as 2,000 women in Buncombe County and 13,000 women in HSA I.

I've only described two of the guidelines for selecting women who will benefit from a breast MRI scanner. The guidelines outline five specific populations of women for which evidence proves breast MRI can detect breast cancer. Our petition, which will be submitted in August, provides greater detail regarding these guidelines.

Based on the 2007 SMFP, residents currently have access to dedicated breast MRI services in HSA II. Residents in HSA III will have soon have access to dedicated breast MRI services pursuant to the 2006 SMFP adjusted need determination. Residents of HSA I do not have access to dedicated breast MRI services. It is well known that it is very difficult for residents of western North Carolina to travel long distances for healthcare services. Furthermore, the 2007 American Cancer Society guidelines identify a greater population of women who can benefit from breast MRI. A dedicated breast MRI scanner is needed in Buncombe County to serve HSA I residents.

Hope is a skilled women's cancer center experienced in treating women with cancer such as breast, ovarian, and cervical cancer. We have provided women's healthcare services to patients of western North Carolina for over 14 years.

Hope physicians are primary investigators for the Gynecologic Oncology Group in western North Carolina. The GOG is the primary study group for women's cancers in the United States. Hope is also a cooperative group with the American College of Surgeons - Oncology Group and participates in breast cancer trials. In addition Hope participates in other clinical trials through Cancer Trials Support Unit which is a clearinghouse to facilitate enrollment in clinical trials that are sponsored by other cooperative groups. The National Cancer Institute (NCI) works with the GOG, other cooperative groups and most of the major cancer centers to develop new treatments or fine-tuning existing ones. These changes usually lead to improving the standard of care.

Hope seeks to improve the standard of care in western North Carolina via an adjusted need determination for a breast MRI scanner.

We feel there is a clear need for a dedicated breast MRI scanner in Buncombe County. We hope you will support us in this effort by approving this petition for an adjusted need determination. Thank you for providing me with the opportunity to discuss this important issue.

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Technology and Equipment Committee Meeting

August 29, 2007

MRI MATERIAL

Material Related to

MRI Comments – Upright MRI

NCHA
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August 3, 2007

Medical Facilities Planning Section
Division of Health Service Regulation
2714 Mail Service Center
Raleigh, NC 27699-2714

Dear Mr. Elkins and members of the State Health Coordinating Council:

The Proposed 2008 State Medical Facilities Plan (SMFP) includes an adjusted need determination for four demonstration projects of one fixed multi-position MRI scanner each. For the following reasons, NCHA recommends that the Council re-establish this need determination at the level of two scanners that was recommended by the Technology & Equipment Committee.

- To date no CON applications for this technology have been submitted, nor have any requests to replace existing MRI equipment with this technology been filed. Given the apparent limited interest in the technology, we recommend that the SHCC move cautiously by establishing fewer need determinations, as it has with previous specialized MRI scanners. Establishing two demonstration projects will enable a careful assessment of the clinical benefits and the utilization and payer mix trends of the technology.

- The demonstration project, as described in the Proposed 2008 SMFP, places the four scanners into the inventory after the first year of operation. If patient volumes for the upright scanner prove to be low, a corresponding drop in the average scan volume per machine could inhibit the need for additional full-service MRIs in the service area. Establishing two demonstration projects improves the chance of success for each of the upright scanners while reducing the chance of a negative impact to the MRI service areas where they are developed.

- As a 0.6T MRI system, the scanners field strength is lower than that of most equipment in the state. Many of the lower-field strength MRI systems are being phased out by MRI service providers in North Carolina.

- The recommendation of two scanners by the Technology & Equipment Committee already exceeds the number requested by Governor Easley in the 2007 SMFP and is comparable to the number approved prior demonstration projects.

Thank you for the opportunity to comment on the Proposed 2008 State Medical Facilities Plan and please feel free to contact me if you have questions

Sincerely,

Mike Vicario
Vice-President of Regulatory Affairs

Raleigh PH
8-1-07
Upright MRI

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August 1, 2007

Good afternoon. My name is Ruben Fernandez, and I am here on behalf of myself, and of Senator Galifianakis to comment on the allowance of four Certificates of Need for Upright MRI machines.

First of all, I would like to than the Governor, Mike Easley, for recognizing the need for these machines. Second, I would like to thank the Committee for recommending that four of them be placed in this State. The way that our Certificate of Need process works relies on the hard work of a lot of people, and it is only through them that the State of North Carolina can continue to have state of the art medical facilities.

The upright MRI has been recognized by the United States Military, and by Congress as an important diagnostic tool, and for its invention, Dr Damadian was awarded the Congressional Inventor of the Year award this year.

For those of you here who are not on the Technology committee, these upright MRI machines differ from the MRI machines that we currently have in North Carolina in that they can take images of patients in all positions, not just lying down, but standing up, sitting, standing on their heads, whatever. The great benefit of this is that they can take images of the human body while it is under the stress of having weight put on its joints, spine, etc...

While these machines are not a replacement for the traditional MRI machines we already have in place, they do provide a specialized type of scans for doctors, like orthopedic surgeons, who need to work on a patient's spine or joints, or other parts of the body that move and shift under load. It is because these machines are specialized that we need these Certificates issued to place them. A specialized MRI will always serve a smaller percentage of the population than a more general purpose MRI, combine that with the fact that these MRI machines are not as profitable to operate, and it is easy to see why they have trouble competing for a CON with the traditional MRI machines that keep getting put in.

Right now, if my doctor wants to look at an MRI of my spine while I'm standing up, I need to fly to another state to get it done. I don't think that's the kind of medical service we want in this state.

There are several Orthopedic centers in North Carolina who want access to these machines. Some of them have already tries to put them in, they just need a Certificate like the one proposed to be issued so they can put them in.

With that, I thank you for your time.

Carolinas HealthCare System

James T. S. Hunter
Chairman

Michael C. Lancaster, FACHE
President & CEO

August 2, 2007

Dan A. Myers, M.D.
Chairman, North Carolina State Health Coordinating Council
c/o Medical Facilities Planning Section
Division of Health Service Regulation
701 Barbour Drive
Raleigh, North Carolina 27603-2008

Dear Dr. Myers:

I am writing in regard to the demonstration project for four fixed multi-position MRI scanners contained on page 139 of the Proposed 2008 State Medical Facilities Plan (SMFP). I am recommending this section of the proposed SMFP be changed to include only two multi-position scanners (one for each side of the state). The rationale for this recommendation is summarized below:

- ☐ After careful review of the key issues and position outlined by Axiom Imaging in its petition to include one scanner in each of the state's HSAs, Medical Facilities Planning staff recommended to the Technology and Equipment Committee that one such scanner be placed in the 2008 SMFP. After its consideration, the Technology and Equipment Committee recommended two scanners statewide. My recommendation is congruent with the direction provided by the Technology and Equipment Committee.

- ☐ On May 30, the SHCC voted to increase the Technology and Equipment Committee recommendation from two scanners to four. During this SHCC meeting, I do not believe the members of the SHCC had full and complete knowledge of the facts surrounding this technology as follows:

    - Based on our research, the manufacturer of the demonstration scanner is Fonar. To date, it appears Fonar has sold approximately 120 scanners worldwide over the past eight years. With the proposed demonstration project as is, North Carolina is proposing to add three percent to the worldwide market inventory

for this particular scanner. These data points provide insight into the magnitude of placing four scanners in the SMFP in a single year.

- The proposed scanner is a 0.6T MRI system. Image quality for this particular scanner is noticeably inferior to 1.5T and 3.0T systems. The current replacement market for MRI in North Carolina is showing a high preference for advanced versions of 1.5T MRI systems and a growing installation of 3.0T MRI systems. 0.6T scanners and similar lower field strength MRI systems have been or are being phased out by several owners of this equipment in the state.

- Four multi-position scanners represent a 36 percent increase in the total number of MRI scanners in the 2008 SMFP as the proposed SMFP already shows the need for 11 fixed scanners statewide. On a comparative basis, adding four additional scanners in a demonstration project appears significantly aggressive as four of 15 additional scanners are arbitrary in nature versus the 11 scanners that are based on the need methodology formula. *It is noted there is no prohibition against proposing an upright MRI scanner in response to the 11 scanners already cited as needed in the plan.*

- It is also noted that the multi-position scanner proposed in the demonstration project has been available for sale in North Carolina for the past six years. During this period, a total of 77 additional fixed MRI scanners have been approved under the state health planning process (2002-2006 SMFPs). During this period of time, no physician practice, imaging center or hospital has purchased the multi-position scanner proposed in this demonstration project.

❒ Including two scanners in this demonstration project will allow the state to evaluate the benefits and the utilization and payer mix trends of the project before additional scanners of this type are placed in the SMFP. This approach is more consistent with how the state has handled the past three MRI demonstration projects, including breast, extremity and pediatric, whereby only one scanner was available under the initial demonstration.

We appreciate the opportunity to offer these comments as you, your staff and the SHCC work to finalize the 2008 State Medical Facilities Plan over the next several months. If you should have any questions regarding the above information and comments, please give me a call.

Sincerely,

F. Del Murphy, Jr.
Vice President

SHCC Public Hearing Presentation Comments for Support of Adjusted Need Determination for 4 Demonstration Projects for Multi-position MRI Scanners

Presented by Charles Wilson, Chief Executive Officer
Triangle Orthopaedic Associates
Durham, North Carolina

July 24, 2007

Good afternoon, my name is Charles Wilson and I am the Chief Executive Officer for Triangle Orthopaedic Associates. I am here today to speak in support of the adjusted need determination published in the Proposed 2008 State Medical Facilities Plan, for four demonstration projects for multi-position MRI scanners to be located in western and eastern North Carolina.

As has been discussed and debated by members of the SHCC's Technology and Equipment Committee in meetings this past winter and spring, recent studies have concluded that imaging of the spine in the erect standing and seated positions adds significantly to the diagnostic ability of MRI. We note as significant that Governor Michael Easley, in approving the 2007 State Medical Facilities Plan, specifically requested the SHCC to study the need for an upright MRI scanner, and consider including such a need in the 2008 SMFP.

The upright, multi-position MRI scanner is a fast scanning, high-resolution whole body imaging system operating at 0.6 Tesla. Also known as the "Stand-Up MRI", it is the only whole-body scanner with the ability to scan patients in a multitude of positions, including in weight-bearing positions and in the positions of symptoms or pain. The intent of allowing CONs for multi-position MRI scanners is to benefit patients for whom conventional MRI scans have proven uninformative as to their ailments, as is often the case for those who experience back and joint pain when standing, sitting or moving, as opposed to simply lying down. The diagnostic information yielded by the upright MRI scanner offers superior ability to obtain accurate diagnoses when compared to recumbent imaged obtained by conventional MRI scanners. Our orthopedic physicians, who deal with the spine and its injuries, envision real benefits to patients from this technology, and are anxious to see this imaging technology in North Carolina. A multi-position MRI scanner gives a more accurate diagnosis of the spine and joints in the actual positions that cause pain. This allows for a more accurate diagnosis of the problem, and enables a higher success rate for orthopedic surgery.

In addition, claustrophobia is a major deterrent to having an MRI scan for a significant portion of the population. Barring sedation, many patients scheduled for MRI scans in conventional scanners cannot complete the

procedure due to claustrophobia.[1] A multi-position MRI scanner removes barriers that discourage or prevent claustrophobic individuals from having needed MRI scans, by providing the scans in an open environment, as opposed to being scanned in a tight cylinder, as is the case in a conventional MRI scanner.

As the SHCC already knows, the multi-position MRI scanner has gained acceptance throughout the United States, including in all the states surrounding North Carolina. Virginia has three, and Georgia, Tennessee and South Carolina each have one such scanner.

Given competitive realties of fixed MRI reviews, it is extremely difficult for specialized MRI scanners (like an upright MRI scanner or an extremity MRI scanner) to serve as many patients as a general use scanner. Therefore, in a competitive MRI review, a specialized MRI scanner can be considered by the Agency to be a less effective alternative compared to a general use MRI scanner. Inclusion of this adjusted need determination in the Final 2008 SMFP will enable North Carolina residents to have access to equipment that is demonstrated in other states to have significantly better ability to visualize pathology compared to recumbent MRI imaging. Failure to allow the use of this technology in North Carolina may increase long-term health costs, because existing equipment is more likely to mask pathology

[1] Journal of European Radiology, Vol 3, Issue 4, August 1993

in recumbent imaging (especially spinal images). North Carolina residents have a high frequency of back surgeries. Unfortunately, there is a relatively large number of failed back surgeries in our State. As I stated previously, our physicians believe that upright imaging is needed to best obtain the correct diagnosis. The resulting improved diagnostic imaging will lead to better surgical and non-surgical care of our patients.

TOA features a clinical research program dedicated to the advancement of orthopaedic and musculoskeletal medical care through clinical research and education. Our research is directed toward studying new medications or devices which are intended to improve the quality of or the availability of a treatment for a given disease or symptom. The objectives of clinical outcomes data and information are intended to support, or oppose, new methods of treatment, and to determine what new technology provides the best treatment options for patients (for example, upright MRI scanners).

As already determined by the SHCC when it included the adjusted need determination in the proposed 2008 SMFP, there is clearly a need for multi-position MRI scanners in North Carolina. Furthermore, TOA, along with other healthcare providers, already have the resources in place to make excellent use of such upright scanners. We hope the State Health Coordinating Council will help our North Carolina patients by going

ahead with the proposed plan to allow four upright MRI Scanners. Thank you for providing me with the opportunity to discuss this important issue.

August 3, 2007

Mr. Robert J. Fitzgerald, Director
Division of Health Service Regulation
Medical Facilities Planning Section
2714 Mail Service Center
Raleigh, North Carolina 27699-2714

Dear Mr. Fitzgerald:

I am respectfully submitting our comments with regard to the demonstration project for four fixed multi-position MRI scanners in the Proposed 2008 State Medical Facilities Plan (SMFP). We appreciate the opportunity to offer these comments as you finalize the 2008 State Medical Facilities Plan over the next several months.

1. Demonstration CON's in North Carolina have historically been limited to one device; authorizing two is more than customary. It is felt that four simultaneous CON's would support a separate regulatory class of MR, not a demonstration project. There is a lack of support for multiple projects based the available market and clinical evidence. Our opinion rests that no demonstration project is needed, but if the state wishes to proceed, the study project should limited to one application in 2008, and a second in 2009. This would give prospective demonstration project applicants the opportunity to compete for the first unit; then refine their applications for the second if desired. This approach would foster better crafted proposals, potentially adding to the value of the project data.

2. The argument that this is a vital technology which North Carolina patients need to access is unproven. The Axiom petition offers an emotional appeal which sounds good, but lacks scientific evidence. There is no literature to support actual improved patient outcomes over current evaluation and treatment techniques. What supporting literature is available can be characterized as anecdotal. Evidence based medicine is now the review standard. Several rigorous medical policy review documents are available, all of which conclude that available evidence is poor.

3. The Axiom petition cites literature generated by individuals associated with the only qualified vendor, Fonar. The cases cited would all be identified by existing evaluation processes. The unspoken implication is that more patients can be identified as surgical candidates, and helped by that surgery, and that these patients would otherwise go on needlessly suffering. No evidence is for the reducing the need for surgery is offered as benefit of using the technology. No actual cost savings are claimed or

documented. Using the logic offered in the petition, and then applying known surgical outcome statistics in the same manner as the petitioners use to justify their application, would indicate the potential improvement in patient outcomes is well below 1%, if that.

4. We feel it is appropriate that Demonstration Upright MRI be excluded from the regular MR inventory in the year it is installed, but become a regular part of the inventory for it's location in subsequent years.

5. Upright MRI should be regulated as a standard MRI system and be capable of competing in the market place on its on merits. There should be no special regulatory categories or statuses created.

6. The Demonstration unit cannot be replaced with another MRI unit for a minimum of 5 years. These units have to offer equal and unprejudicial access to all spinal surgeons. As a practical matter, a unit under the control of one physician group or hospital system will not readily be utilized or supported by competing physician groups or hospital systems. In addition, Medicare anti-kickback and Federal "Stark" rules should govern all referrals to the demonstration systems, regardless of payer status, public or private. Violations of this could result in revocation of the project CON.

7. There are ample opportunities for either new applicants or an existing site to replace an existing unit with an Upright MRI system. To date, no conversions have been proposed or have occurred. However, regardless of what form the proposed demonstration project takes, existing operators or future applicants for CON's can elect to adopt or propose upright MR systems at any time under the existing regulations. There is no substantial barrier to the adoption of this technology other than its own intrinsic qualities.

8. The current replacement market for MR in North Carolina is showing a high preference for advanced version of 1.5T MR systems, along with a growing number of installed 3.0T systems. 0.6T and similar lower field strength systems have been, or are being phased out by current owners of this equipment in North Carolina.

9. There are 120 Fonar systems installed worldwide after more than 8 years of purchase availability. There are no current Fonar installations in North Carolina. This project proposes to add three percent to the world installed base and most likely more than 20% of FY 2007 sales.

10. The Fonar 0.6T MR system enjoys all of the advantages and limitations of a lower strength MR system. Image quality is noticeably inferior to 1.5T and 3.0T systems. The image plane thicknesses used are usually greater than at 1.5T in order to reduce image noise and improve image appearance. This creates small lesion resolution issues, particularly in the

cervical and thoracic spines. Symptomatic small disc herniations can be missed, along with small spinal cord lesions.

11. Low field MRI systems examinations can last as much as 3 times as long as high field systems. This results in an increase in the likelihood of patient motion, thereby adding to the inaccuracies of a low field system.

12. Upright MRI may offer limited value in flexion-extension MRI, which presents a challenge in typical 1.5T and 3.0T systems.

13. Some operators accept lower image quality images to reduce examination times and increase patient throughput.

14. Historical demonstration projects focused on Breast, Orthopedics, and Peds have been approved on a singular basis and have limited the approved applications appropriately. Given that the only compelling rationale offered by the proponents of this technology support this demonstration project has been for spinal imaging, each demonstration project MRI should be limited to only performing spinal imaging during this project duration. This should not cause a community hardship since there is presently no evidence to indicate any significant access problems for MRI services in the HAS. Limiting imaging on this demonstration as well would maximize the date value of the Upright MR Demonstration Project. Such a qualification is both desirable and appropriate given the nature of the project.

15. An alternative spinal axial loading device that can be used in current installed conventional MR systems in the state exists and can be readily obtained and employed if current or future operators so desire. The arguments that upright MRI systems the only ways to evaluate the lumbar spine under axial loading conditions are not entirely correct. This spinal axial loading device, titled the Portal Gravity System, Portal Medical, Logan Utah, is available for purchase. There is a paper validating that this device effectively simulates upright imaging results. Like upright MRI, this approach lacks compelling outcomes evidence at this time.

16. There is no evidence to support the value in imaging post operative spinal patients in an upright position.

17. An application for a unique CPT code for upright MRI was received by the CPT Editorial Panel and denied due to a lack of compelling evidence.

18. The sales literature cites that placing a patient in a position that recreates their pain can assist in the localization of abnormalities that may not be seen in a recumbent state. The patient pain stimulus would most likely be a reason for motion during the long exam times exhibited on low field systems.

19. Orthopedic work will be marginal similar to open MRI technology. Lower field strength limits accuracy, image quality. Likewise, the ability to offer upright imaging in orthopedics has limited utility and greatly increases the probability of patient motion.

20. Extensive research along with current clinical Breast Cancer imaging supports a temporal approach unattainable with low field systems.

21. Intra and Extra-cranial blood flow dynamics do change in an upright posture. Again, this may offer limited utility as an adjunct imaging procedure. More research is need in this area.

22. Facility must operate a minimum of 66 hours per week.

23. There should be full disclosure of the MR system and site ownership including names of all physician investors and their relatives. Also, disclosure of any consultant payments, lease arrangements, and assigned billing arrangements.

24. Annual reports should be made to the CON and Medical Facilities planning Section reporting:

    - The number of exams performed in an upright position.
    - Total number of exams.
    - The CPT code data for all performed exams.
    - Patient payer mix of insured, under-insured, and un-insured.
    - Referring doctor and patient origin data.
    - Itemized billing with specifically identified technical and professional charges and who provided those services as actually submitted for payment.
    - Facility revenue and operating expenses.

Sincerely,

CHARLOTTE RADIOLOGY, P.A.

Mark D. Jensen
Chief Operating Officer

MDJ:js

Rec'd @ July 30, 2007 Public Hearing in Wilmington

July 30, 2007

North Carolina State Health Coordinating Council
Proposed 2008 State Medical Facilities Plan
Coastal AHEC, Wilmington, North Carolina

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JUL 30 2007
Medical Facilities Planning Section

Submitted by:
Mark Ragozzino MD
Orthopedic and Neurologic Imaging Specialist
Delaney Radiologists
1025 Medical Center Drive
Wilmington, North Carolina, 28401

The 2008 State Medical Facilities Plan proposes a demonstration project consisting of four 4 multi-position, fixed site MRI scanners placed throughout North Carolina. This proposed demonstration project is in response to a petition filed by one for-profit corporation, Axiom Imaging. Axiom imaging is a Las Vegas, Nevada corporation.

The 2007 State Medical Facilities Plan rejected the multi-position MRI demonstration project. We are perplexed to see this demonstration project appear again in the proposed 2008 State Medical Facilities Plan.

This demonstration project is an end run around the well-established need determination process under the guise of medical research. Additionally, the demonstration project flies into the face of the proposed 2008 State Medical Facilities Plan. The plan states that there is no need for additional, fixed-site, open or closed MRI machines in North Carolina.

The multi-position MRI machines called for by this demonstration project are sold only by Fonar Corporation of Melville, New York. The major MRI manufacturers such as General Electric and Siemens have rejected this multi-position design.

Although Fonar MRI equipment has been available to all MRI providers in North Carolina for years, no Fonar MRI machine is installed in North Carolina. The market place, reflecting the needs of North Carolinians, has rejected multi-position, Fonar MRI machines due to poor image quality, cost and other impracticalities.

North Carolina MRI facilities include not-for profit research institutions, non-profit community hospitals, for- profit national corporations and for-profit community medical groups. These varied entities cover a broad spectrum of imaging needs. All have rejected the Fonar multi-positional MRI. .

The purported necessity for the demonstration project is for imaging the spine under load. This argument is specious as a validated spinal loading device is currently available for existing MRI machines. This accessory placed on an existing, standard, open or closed MRI machine can provide higher quality diagnostic information at less cost.

This demonstration project will not provide useful efficacy data. However, it will increase state medical expenditures. Most importantly, it has potential to harm health care consumers. The only beneficiary of this demonstration project is Axiom Imaging, a for-profit corporation based in Las Vegas.

If a useful demonstration project is truly desired, a single multi-position MRI machine should be placed within and under complete control of an academic research center such as Duke or UNC-Chapel, in immediate vicinity of several other competing MRI machines. The demonstration project should specify the testing of well-defined, medically relevant hypotheses and study results should be published in respected, peer-reviewed journals.

The demonstration project proposed by Axiom Imaging for the 2008 State Medical Facilities Plan is disingenuous and simply a ruse to circumvent the well-established need determination process of North Carolina.

MedQuest Associates, Inc.'s
SHCC Public Hearing Comments
Regarding the Adjusted Need Determination
For 4 Demonstration Projects for Multi-Position MRI Scanners
August 1, 2007

MedQuest Associates, Inc. ("MedQuest") is one of the country's leading independent outpatient imaging providers. It operates more than 90 outpatient imaging centers in 13 states including 14 facilities in North Carolina. For more than a decade, MedQuest has actively been involved in the evaluation and selection of MRI scanners for its facilities.

The multi-position MRI ("upright") scanner does not represent cutting edge technology as some would have the State of North Carolina believe. This technology has been available in the commercial marketplace for several years; thus, providers in North Carolina have had ample opportunity to replace existing systems and/or file Certificate of Need applications for "upright" scanners. Further, the "upright" scanner is a 0.6 Tesla system, which provides it no specific image quality advantages over 0.7 Tesla open systems or 1.5 Tesla and 3.0 Tesla closed bore systems. None of the medical teaching facilities in North Carolina have filed applications or petitions for "upright" scanners, indicating that the unique aspects of the unit are of limited clinical value and do not warrant a special clinical "demonstration". Finally, the multi-position MRI scanner proposed does not require a unique CPT code, which means it has not received any special designation by the CPT Editorial Panel.

For the above reasons, MedQuest does not believe that the State Health Coordinating Council should even approve one demonstration project for a multi-position MRI scanner, much less four scanners of this type. MedQuest believes that the primary intent of this request is to acquire additional MRI scanner capacity outside of the normal MRI methodology. Any current provider of MRI services has the ability to upgrade or replace an existing MRI scanner. To date, none of the MRI providers in North Carolina has chosen to acquire this type of MRI scanner through that process. Current providers and applicants for MRI services also have the opportunity through the CON process to

propose a multi-position scanner in a normal CON review. There is no need for a demonstration.

If the SHCC decides to proceed with a demonstration project, then MedQuest requests that the SHCC consider the following:

1. **Limit the demonstration project to one multi-position scanner for the State.**

This request is consistent with prior demonstration projects such as the dedicated breast MRI scanner and pediatric MRI scanner.

2. **Limit the use of the multi-position scanner to spine-only studies and in an upright position.**

Since the petitioner has argued that the purpose of the multi-position scanner is to allow patients in need of spine studies to stand upright during the exam, then the approved applicant should be limited to these studies. This is consistent with the theory of allowing demonstration projects and with the requirements previously made of the dedicated breast MRI scanner and pediatric MRI scanner.

3. **Do not allow the provider to replace the multi-position scanner with a conventional fixed or mobile MRI scanner.**

In order to prevent demonstration projects from becoming a loophole method for obtaining a fixed MRI scanner, the SHCC should mandate that a provider approved for this demonstration project cannot replace the multi-position scanner with a conventional fixed or mobile MRI scanner. If the scanner becomes obsolete after five or ten years and the provider cannot replace the equipment with another multi-position scanner, then it should be required to relinquish its certificate of need for the project.

Thank you for the opportunity to comment on this issue.

Bruce Elder

Bruce Elder
Vice President, Development
MedQuest Associates, Inc.

Wake Forest University Baptist

DFS Health Planning
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AUG 02 2007

Medical Facilities
Planning Section

August, 2 2007

Michael L. Freeman
Vice President
Strategic Planning

Telephone: (336) 716-5097
Fax: (336) 716-2879
freeman@ufubmc.edu

Mr. Robert J. Fitzgerald, Director
Division of Health Service Regulation
Medical Facilities Planning Section
2714 Mail Service Center
Raleigh, North Carolina 27699-2714

Dear Mr. Fitzgerald:

I am writing to reiterate the concern Carolina's Healthcare System has expressed with respect to the proposed demonstration project for four fixed multi-position MRI scanners contained on page 139 of the Proposed 2008 State Medical Facilities Plan (SMFP). I am also recommending this section of the proposed SMFP be changed to include only two multi-position scanners (one for each side of the state). Including two scanners in this demonstration project will allow the State to evaluate the benefits, utilization and payer mix trends of the project before additional scanners of this type are placed in the SMFP. This approach is more consistent with how the State has handled the past three MRI demonstration projects, including breast, extremity and pediatric, whereby only one scanner was available under the initial demonstration.

The rationale for this recommendation as summarized by Carolina's Healthcare System includes the following points:

- Our recommendation is similar to the original direction provided by the Technology and Equipment Committee to include one scanner to represent each of the three eastern and three western HSAs, which would equate to only two scanners statewide.

- On May 30, the SHCC voted to increase the Technology and Equipment Committee recommendation from two scanners to four. During this SHCC meeting, I also believe the members of the SHCC did not have full knowledge of the facts surrounding this technology as follows:

    - Based on our research, the manufacturer of the demonstration scanner is Fonar. To date, Fonar has sold only 120 scanners worldwide over the past eight years. With the proposed demonstration project as is, North

Carolina is proposing to add three percent to the worldwide market inventory for this particular scanner.

- The proposed scanner is a 0.6T MRI system. Image quality for this particular scanner is noticeably inferior to 1.5T and 3.0T systems. 0.6T scanners and similar lower field strength MRI systems have been and/or are being phased out by several owners of this equipment in the State.

- It is also noted that the multi-position scanner proposed in the demonstration project has been available for sale in North Carolina for the past six years. During this period of time, no physician practice, imaging center or hospital has purchased the multi-position scanner proposed in this demonstration project.

I appreciate the opportunity to offer my recommendation and comments to you as your staff and the SHCC work to finalize the 2008 State Medical Facilities Plan over the next several months. If you should have any questions regarding the above information and comments, please feel free to call me at (336) 716-5097.

Sincerely,

Michael L. Freeman

Michael L. Freeman
Vice President, Strategic Planning

Greensboro PH
7-20-07
MRI
TOM

Comments on the petition for an upright MRI
Proposed NC 2008 SMFP
David C. Clark MD
Greensboro Radiology
July 20,2007

The proposed demonstration project for upright MRI is opposed for the following reasons:

1. There is a lack of scientific evidence showing improved patient outcomes or more accurate diagnosis using an upright MRI as opposed to the current standard MRI systems. The Axiom Imaging Petition claims a "Failed Back Syndrome" of 5% to 40% following spine surgery, and implies that their upright MRI would improve this rate, but provide no evidence to support this claim. The Axiom petition claims that North Carolina residents are being harmed by lack of access to this technology, but upright MRI equipment has been available for 8 years and no units have been purchased in North Carolina which speaks to lack of demand for this technology in the marketplace. Upright MRI should be regulated as any other MRI system is in North Carolina. There are hundreds of orthopedic surgeons in North Carolina, none provide written support for this technology in the petition.
2. The criteria for approving demonstration projects for MRI has not been defined. This opens the door for vendors and providers to lobby to obtain profitable technology outside the current CON process. Without written criteria, the DFS runs the risk of creating a precedent for requests for multiple future demonstration MRI projects based on vendor and medical provider financial gain, rather than improvements in public health. Without clarity of the rules, it is likely that future demonstration project requests will appear with minor variations from current technology, as a means to get new magnets in the marketplace. I suggest that this and future MRI demonstration project requests be suspended until written criteria are developed that specify:
   a. Criteria for making a petition for a demonstration project for MRI
   b. Criteria for approval for the demonstration projects
   c. Data to be collected and how this data will be used to make future decisions
3. Petitions for MRI demonstration projects based solely on technology variations should be denied. Technology is constantly changing, and today's latest and greatest technology may be obsolete by the time the demonstration project is operational.

4. The petition for upright MRI should be disapproved because there is no evidence that it will benefit the health of North Carolinians. The primary beneficiary of this technology will be the vendor selling the product as there is only one vendor producing this equipment, and the provider of the service. The vendor should compete in the marketplace for sales, through the replacement process of existing MRI units.

5. Upright MRI is a one trick pony. Its only proposed benefit would be to perform MRI under upright axial loading conditions. However, it is a 0.6 Tesla unit which inherently has longer scan times and inferior image quality than a standard 1.5 Tesla unit. This combined with upright scanning is likely to have a higher incidence of patient motion. Therefore, if the upright MRI demonstration project is approved, I recommend that the only procedure performed on the scanner is upright imaging in order to gather data to make future determinations regarding the validity of the technology. Limiting imaging on the demonstration MRI to upright imaging is appropriate and consistent with prior restrictions placed on breast and pediatric CON demonstration projects. It would also prevent substandard imaging on equipment that could be better performed on existing high field technology.
6. There is not a unique CPT code for upright MRI. This was submitted to the CPT Editorial Panel but denied. Without a unique CPT code, this procedure is considered experimental and may not be reimbursed by some carriers.
7. Insurance companies and Medicare are attempting to reduce imaging utilization; the upright MRI would have the opposite effect by bringing in a new unproven technology which would promote experimentation. Lacking any defined criteria for performing upright spinal MRI makes selection of patients for this technology arbitrary.
8. Should the demonstration project be approved, appropriate data should be collected from the approved site so that future determinations can be made regarding the technology. If approved, one upright MRI scanner should be adequate to gather data on the validity of this technology, not the four scanners currently requested. At minimum, the following should be included:

    - The number of MRI examinations performed on the unit
    - The total number of upright MRI studies performed on the system
    - CPT code data for all examinations
    - Patient payer mix including Medicare, Medicaid, insured and uninsured
    - Referring physician examinations
    - County of residence of all patients having the examination
    - The demonstration MR facility must operate a minimum of 66 hours per week. The facility revenue and operating expenses should be included in the reporting documents.
    - Full disclosure of the MR system and site ownership including the names of all physician investors and their relatives. Disclosure of any consultant payments, lease arrangements, and assigned billing arrangements should be disclosed.
    - Documentation of the number of cases where outcomes and or patient management decisions were impacted by the upright MRI

WAKE RADIOLOGY

CONSULTANTS, P.A.

DFS Health Planning
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2007

Medical Facilities
Planning Section

July 24, 2007

Mr. Tom Elkins
Medical Facilities Planning Section
Division of Facility Services
2714 Mail Service Center
Raleigh, North Carolina 27699-2714

RE: Comments Submitted for Public Hearing Proposed 2008 State Medical Facilities Plan: Upright MRI Demonstration Projects

Dear Mr. Elkins,

The following comments are in reference to the proposed 4 Upright Fonar MR demonstration projects in the 2008 Plan. Upright MRI is exclusively manufactured by a sole source vendor, Fonar, which has sold approximately 120 systems worldwide in the past eight years. Nothing in the current CON process discriminates against Fonar's technology, any future applicant or replacement system can obtain permission to install or replace an existing MR with an Upright Fonar system under the current methodology. The inclusion of this technology as a demonstration site is undoubtably manufacturer driven. Frankly, 4 demonstration sites equal four sales for Fonar. Given that there is no current restriction on Fonar selling these instruments to North Carolina providers, why then is there a need for 4 demonstration projects?

If the State has determined the necessity for an Upright MR demonstration project, one site should accomplish the task not unlike the breast MR, pediatric MR, and extremity MR demonstration projects now in process.

Indeed, if the State believes there is a need for more than one Upright MR demonstration project, then the additional allocations for these projects should be granted to one or more of our four academic teaching centers. For if the demonstration projects are to prove or disprove the technology, who better to run the additional projects then Duke, Wake Forest, UNC, or ECU?

DIAGNOSTIC RADIOLOGY
[illegible]

RADIATION ONCOLOGY
Andrew S. Kennedy, M.D.
Scott E. Sailer, M.D.
William A. Dezarn, Ph.D., DABR

ADMINISTRATOR
W. H. Johnson

BUSINESS MANAGER
B. V. Hill

3949 Browning Place • Raleigh NC 27609
www.wakeradiology.com

The forgoing discussion highlights the need for the Division of Facility Services to establish criteria for demonstration project petitions in an effort to discourage manufacturer driven sales agendas from overwhelming the State's process.

At the end of the day, Upright MRI is just a technology variant currently available through the existing process. If the State approves the demonstration project, one site should provide the necessary results. Any other provider can obtain this technology through the normal application or replacement process now in place.

Sincerely,

Robert E. Schaaf, MD
President and Managing Partner
Wake Radiology

Asheville PH
July 13, 2007
Jim Montgomery
Ninth posting MRI

Comments for Public Hearing
Proposed 2008 State Medical Facilities Plan
Asheville
RE: Multiposition MRI-Demonstration Project(s)
13July2007

1. The original suggestion for the demonstration project was for one upright MRI scanner for the HSAs I-III and one for HSAs IV-VI. This was changed to a total of FOUR scanners. The proposed 2008 SMFP on Table 9Q(1) shows that there are only 11 MRI scanners in the total State's need determination. Thus the Plan is recommending adding 36% more scanners to the Plan that the original need determination. There is no reason to add this many multiposition scanners, especially given that they are a demonstration project.

2. Multidirectional scanners are "Low Field" technology. All the medical centers in North Carolina are installing 1.5 or 3.0 T technology, not 0.7 T. This project seems to be going the wrong direction.

3. Some argue that patients are being disadvantaged by not having this technology available. This is ridiculous, these scanners have been available for years. There are none of these scanners in use in NC because doctors and hospitals have chosen not to buy them. Asheville Radiology owns or operates six scanners. We consider this technology to be inferior and out of date

4. The literature regarding multipositional MRI is commonly biased by a manufacturer's sponsored outcome, not based on evidence based medicine.

5. If any of these scanners ultimately appear in the Plan, they should be *limited to scanning only the spine* and all numbers carefully reported.

6. Most importantly, the *scans must all be done in the upright position*, as this is the reason the scanners were added to the Plan.

7. If hospitals or physician groups feel they need a multipositional MRI, they have the option of replacing existing equipment with a multipositional MRI.

8. There is no credible clinical outcome data to support a multipositional MRI scanner over a conventional scanner.

9. The multipositional scanners are very expensive. Absent positive clinical data and considering the low field technology, there is no justification to add one to the Plan, much less four.

10. The CPT Editorial Panel refused to provide a unique code for upright MRI because of the lack of meaningful outcomes data showing its superiority over conventional MRI.

11. Image quality on a 0.7T MRI scanner is inferior to 1.5T or 3.0T, no matter what direction the magnet is oriented.

12. 0.7T magnets are slower, result in more patient motion, and are more likely to miss small abnormalities because of technical limitations.

13. Abdominal and vascular MRI are of very low quality at 0.7T. Thus, utilization of these scanners will be limited.

14. Fonar makes the multipositional scanner. It has no installations in North Carolina and only a few dozen in the world. No major vendor of MRI equipment (GE, Siemens, Philips) is making a multipositional scanner.

15. If this demonstration project is allowed and a hospital – or more likely, a physician practice – takes on one of these scanners, it should not be replaced for a minimum of five years.

16. CPT code data should be generated and reported to the Agency for all examinations.

17. The patient payer mix must be reported as part of the demonstration project and those results should mirror the region's demographics.

18. To insure compliance with State and Federal Law, disclosure of the magnet's owners (and their relatives), physician investors, consultant payments, and any lease arrangements should be reported to the Agency.

19. Previous demonstration projects have limited utilization of the project MRI scanner to Breast and Pediatric imaging. This project, if implemented, should be limited to the spine and as mentioned above, should be performed upright.

20. Detailed billing data should be reported to allocate technical and professional charges to the provider that actually performed the service.

21. If NC were to allow 4 multipositional scanners in the 2008 Plan, we would likely be placing more of these scanners in our state than any other state in the country. These are uncommon scanners in the marketplace simply because their quality, speed, resolution, and cost [redacted] cannot compete with modern scanners.

22. If a demonstration project is approved, allocation of ONE scanner for demonstration is sufficient. This will allow data to be collected and analyzed to determine if any additional scanners are justified.

Summary: Multipositional MRI is a perfect solution to a problem that does not exist. The numerous experts in our prestigious medical centers and private practices in North Carolina have chosen *not* to buy upright scanners, even though they have been on the market for years. They are too expensive, too slow, and image quality is inferior to scanners currently being sold by most vendors. Evidence based medicine fails to show a driver for this technology.

Rec'd @ July 24 2007 Greenville Public Hearing.

ERI Eastern Radiologists, Inc.

Providing Subspecialty Imaging and Interventional Services to 29 Counties through University Health Systems of Eastern Carolina

Comments for Public Hearing regarding Multi-Position MRI Demonstration Projects
Proposed 2008 State Medical Facilities Plan
July 24, 2007

Eastern Radiologists, Inc. has significant concerns regarding the proposed demonstration project for upright MR for the reasons outlined below:

1. The primary issue is that there is insufficient scientific evidence related to clinical outcomes showing that a multi-positional MR scanner improves patient outcomes or provides more accurate diagnosis than current standard MR systems. The ideal demonstration project would require that the upright MR be placed in an academic medical center or other site where diagnosis and patient outcomes can be compared to standard 1.5 T high field systems in a well designed research protocol which would in turn be published in a peer reviewed medical journal.

2. Demonstration CON's in the State of North Carolina have generally been limited to one device. Authorizing four simultaneous CON's is much more than is needed for a demonstration project and essentially creates a new regulatory class for MR. One unit, or at most two units would be preferable for a demonstration project. The Fonar unit is the only upright MR available. There are 120 Fonar systems worldwide after being on the market for eight years. The proposed four unit CON demonstration project would add 3% to the worldwide installed base and would probably account for more than 20% of Fonar's yearly sales.

3. The only existing upright MR is a 0.6 Tesla system manufactured by Fonar. The majority of hospitals and imaging centers in North Carolina and across the country are moving towards high field systems at 1.5 or 3 tesla due to faster imaging times, higher single to noise, and overall improved diagnostic accuracy. Higher field strength results in improved imaging across a wide range of clinical applications. The Fonar MR system does poor vascular and body imaging due to a combination of its configuration and low field strength. Theses shortcomings likely explain why although new applicants and existing holders of MR CON's have the option to convert existing systems to upright MR, no conversions have yet occurred. The failure of this product to make significant inroads in the MR marketplace, coupled with the lack of concurrent development by other MR vendors, highlights the significant limitations of this design.

4. A unique CPT code does not currently exist for upright MR. The editorial panel recently denied this request. Without a unique CPT code, upright MR may be considered experimental and may not be reimbursed by some carriers.

5. Insurance companies and Medicare are currently trying to reduce imaging utilization. This upright MR demonstration project would have the opposite effect by bringing four

#9 Doctors Park - Greenville, NC 27834 - (252) 752-5000 - (800) 682-6956 - Fax (252) 752-0166 - http://www.easternrad.com

additional units with unproven technology into the state of North Carolina.

6. We are concerned about the lack of criteria for approving demonstration projects in MR. The primary beneficiary of this technology will likely be a single vendor making an unusual product which has not yet been accepted by the medical community. This demonstration project may set a precedent for vendors and providers to lobby for other technologies outside of the CON process as well.

If the state of North Carolina does proceed with this program, we recommend the following requirements:

1. The project should require that the upright MR be placed at a site where diagnosis and patient outcomes can be scientifically compared to standard 1.5 T high field systems in a well designed research protocol which would in turn be published in a peer reviewed medical journal.

2. Full disclosure of the MR system and ownership including all names of physician investors and the relatives, as well as consultant payments, lease arrangements, and billing arrangements including itemized billing with specific identification of technical and professional charges and who provided those services as submitted for payment.

3. Report the referring doctor and patient origin data for each exam should be reported.

4. An annual report should be made to the CON in a medical facilities planning session to report the number of MR exams actually performed in the upright position, the total number of exams performed by the system, the CPT code for all exams, and the patient payer mix of including uninsured and underinsured.

5. Spinal imaging is the major focus of this project and the only application for which this system has been suggested to have an advantage. It is recommended that imaging be limited on the demonstration project CON to only spinal imaging. Similar restrictions have been put in place for breast and pediatric CON demonstration projects in the past and would maximize the data value of this demonstration project.

Sincerely,

Michael McLaughlin, MD, MBA
President
Eastern Radiologists, Inc

Top of Document

Technology and Equipment Committee Meeting

August 29, 2007

MRI MATERIAL

Material Related to

Other MRI Comments

Carolinas Medical Center
Lincoln

Pete Acker
President & Chief Executive Officer

August 1, 2007

Dan A. Myers, M.D.
Chairman, North Carolina State Health Coordinating Council
c/o Medical Facilities Planning Section
Division of Health Service Regulation
2714 Mail Service Center
Raleigh, North Carolina 27699-2714

RE: Comments on the Proposed 2008 SMFP Need Determination for One Fixed MRI Scanner in Lincoln County

Dear Dr. Myers:

On behalf of Carolinas Medical Center-Lincoln (CMC-Lincoln) and the residents of Lincoln County, I want to express my support for the need determination in the *Proposed 2008 SMFP* for one fixed MRI scanner in Lincoln County. As one of only two hospitals in the state with more than 100 beds but without a fixed MRI scanner, we certainly believe there is a need for a fixed MRI scanner to provide adequate diagnostic imaging services to our county's residents, including our inpatients, emergency patients and outpatients. CMC-Lincoln is the sole community hospital provider in the county, providing care to more than 70,000 residents without regard to the patient's age, race, national or ethnic origin, disability, gender, income or ability to pay.

CMC-Lincoln appreciates the Council's willingness to recognize the continuing growth in the number of MRI procedures performed on the mobile MRI unit and the resulting need for a full-time, fixed MRI scanner in the county. We believe that the allocated scanner will expand access to this vital imaging modality for our patients.

If we can be of any assistance to the SHCC as the development of the final *2008 SMFP* continues, please do not hesitate to contact us.

Respectfully yours,

Pete Acker

Peter W. Acker
President and Chief Executive Officer

Fax 919 715-4413

Strategic Healthcare Consultants

DFS Health Planning
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AUG 03 2007
Medical Facilities Planning Section

August 3, 2007

Mr. Tom Elkins
Medical Facility Planning Section
NC Division of Health Service Regulation
701 Barbour Drive
P.O. Box 29530
Raleigh, NC 27626-0530

RE: Comment Regarding Proposed 2008 State Medical Facilities Plan, Chapter 9, MRI Section, Table 9O, Page 133

Dear Mr. Elkin,

I am writing on behalf of Park Ridge Hospital in Henderson County regarding the Proposed 2008 State Medical Facilities Plan. As we discussed, the MRI inventory on page 133 of the Proposed Plan lists Park Ridge Hospital as having both a mobile MRI scanner and a fixed MRI scanner.

Please note that Park Ridge Hospital obtained CON approval to replace its previous mobile MRI scanner with a fixed unit. Park Ridge Hospital has removed the mobile MRI unit from North Carolina and has implemented the fixed MRI scanner in accordance with the CON conditions.

Table 9O shows the "fixed equivalent magnet subtotal" for Henderson County that includes the values of both of the mobile and fixed units which creates the possible impression that both units were simultaneously in use. However this is not the case. The Park Ridge Hospital fixed and mobile MRI units were not in simultaneous use.

Please accept this correspondence as a clarification of the data reflected in the Proposed 2008 Plan. If you have any questions please call me at 336 349-6250.

Sincerely

David French
Consultant to Park Ridge Hospital

Phone: 336-349-6250
Fax: 336-349-6260

Mailing Address
Post Office Box 2154
Reidsville, NC 27323-2154

Top of Document

Technology and Equipment Committee Meeting

August 29, 2007

CARDIAC CATHETERIZATION MATERIAL

Material Related to

Petition-1: Halifax Regional Medical Center

HALIFAX REGIONAL
Patients First.

Petition to the State Health Coordinating Council Regarding the Cardiac Catheterization Need Methodology For the 2008 State Medical Facilities Plan

Petitioner:
Halifax Regional Medical Center
250 Smith Church Road
Roanoke Rapids, NC 27870

Contact:
William Mahone, V
President
Halifax Regional Medical Center
250 Smith Church Road
Roanoke Rapids, NC 27870
(252) 535-8011

PETITION

STATEMENT OF REQUESTED CHANGE

Halifax Regional Medical Center (HRMC) requests the following wording change in the Proposed 2008 State Medical Facilities Plan. On page 183, change Table 9V, Shared Fixed Cardiac Catheterization Equipment Need Determinations to read:

Hospital Service System	Shared Fixed Cardiac Catheterization Equipment Need Determination	Certificate of Need Application Due Date	Certificate of Need Beginning Review Date
Halifax	1	January 15, 2008	February 1, 2008

Based upon information submitted in a special need petition, it is determined that there is a need in Halifax County for one unit if shared fixed cardiac catheterization equipment.

disease represented 290 deaths per 100,000 Halifax County residents compared to the state's rate of 204. Annually, as much as 25 percent of our population dies prematurely because of heart disease. As we move forward in health care from a transaction-based industry to one that focuses on quality outcomes and treatment of diseases, we must enhance concentration on services that help to normalize our death rates and extend quality of life.

Heart Disease Death Statistics

Geographical Area	Number of Deaths 2005	Death Rate 2005	Number of Deaths 2001-2005	Death Rate 2001-2005	Age-Adjusted Death Rate 2001-2005
Halifax	163	289.8	889	313.1	266.2
Northampton	95	440.5	402	369.6	276.3
North Carolina	17,681	203.6	91,056	215.9	226.8
Percent of State					
Halifax		142%		145%	117%
Northampton		216%		171%	122%

Source: http://www.schs.state.nc.us/SCHS/deaths/lcd/2005/heartdisease.html

Statewide, cardiovascular disease accounts for 38 percent of deaths, 24 percent are heart disease related. Yet, death rates are only a proxy measure for disease incidence in a population. We looked at high blood pressure as a proxy measure for prevalence of cardiac artery disease. These data are reported by the North Carolina Center for Health Statistics in its study of health risks of North Carolina adults in 2005.[1] In the study, Halifax and Northampton are grouped in a sector the report calls Northeast North Carolina 1. Days of reported poor health in this sector were almost twice the state average (32 compared to 18 per year). The same report shows that 42 percent of residents of Northeast 1 reported high blood pressure compared to 29 percent statewide. Four out of ten people in the sector are at risk for coronary heart disease.

Value of Cardiac Catheterization

Cardiac catheterization remains the modality of choice for diagnosis and treatment of advanced acute coronary syndrome. It is a key step in the diagnosis and management of coronary artery disease.

Cardiac catheterization is invasive and the procedure carries risks for patients. As technology advances, clinicians and others look for alternative ways to diagnose and treat coronary artery disease. To date, no better alternative exists. In a recent comprehensive review of the medical and invasive management of patients with acute coronary syndrome, researchers concluded that, even with its risks, invasive cardiac catheterization and revascularization are still the best

[1] http://www.schs.state.nc.us/SCHS/pdf/BRFSSReport2005.pdf

Out Migration for Cardiac Catheterization

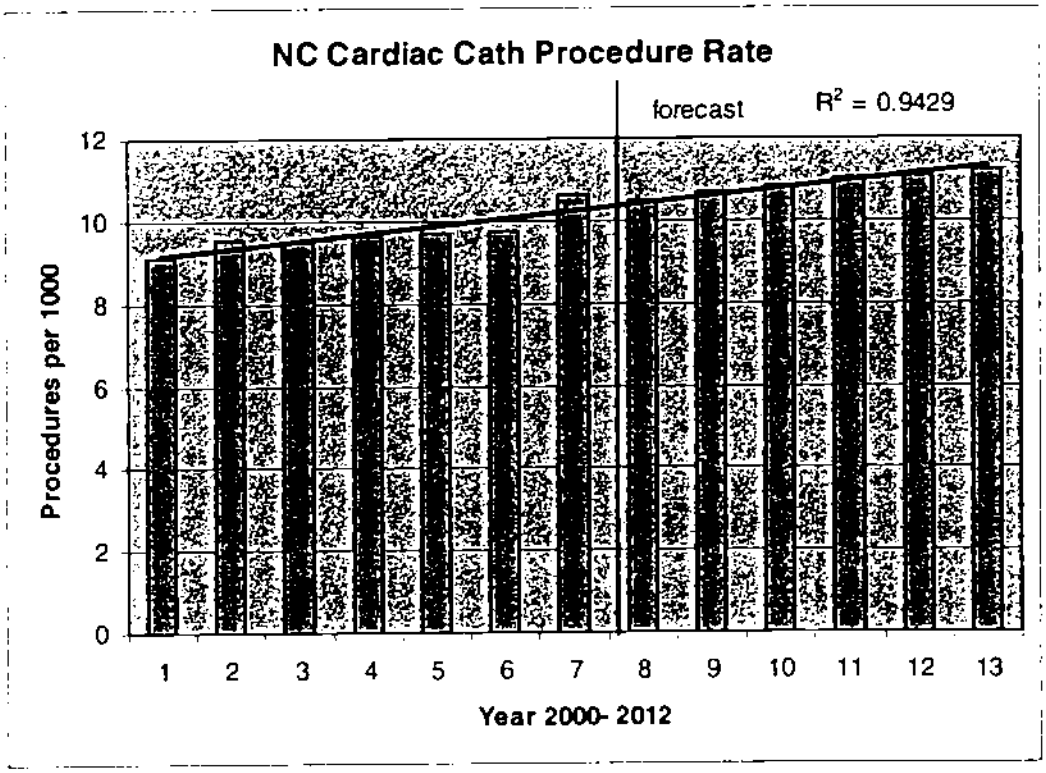
Given the high frequency of demand for cardiac catheterization, it is unreasonable to ask residents of Halifax Regional Medical Center's service area to travel an hour or more, each way, for this critical diagnostic procedure. For many, the time involved means a delay of hours or, more likely, days in getting appropriate treatment. Time involved in stabilizing the patient, determining the diagnosis, arranging medical transport, coordinating care teams at the referral hospital adds up to critical time lost for the patient for whom timely cardiac catheterization is the best solution, not to mention the strain on the referring physician. Hospital administrative and clinical leaders regularly hear frustrated reports from our referring physicians that patients have refused to leave the community to get a cardiac catheterization, when it is clearly the best medical solution.

Today, our physicians and emergency department refer cardiac catheterization patients to Greenville, Rocky Mount and Raleigh, each at least an hour away. However, many patients refuse to make that trip regardless of the exceptional quality available at these centers. For many patients, travel and cost are the ultimate barriers to care.

We have documented evidence that requiring travel outside the service area automatically deters a substantial proportion of our residents from follow up on treatment or diagnostic recommendations. This is true regardless of whether or not they have third party insurance coverage. In probing the reasons, we find that patients make these decisions for many reasons. Direct costs of the procedures or treatments play only a small role in their decision making. Patient reasons for deferral involve their perception of distance from home to the treatment center, fear of travel on the interstate and urban beltways, and distance of the referral center from family and support networks.

Some do agree to travel. Last year, 734 people from Halifax and Northampton Counties sought diagnostic catheterizations. Most went to Raleigh. These numbers represent two people a day -- more than enough to support a shared fixed cardiac catheterization lab. Indeed, the shared fixed cardiac catheterization laboratory is the ideal solution for a smaller community. With only minor modifications, technology now supports both peripheral and cardiac angiography on the same equipment

Moreover, the same disease / environmental factors that cause peripheral vascular disease cause it in the heart. Thus, with approval to offer cardiac catheterization, HRMC could address the full needs of patients who have vascular disease, and could do so with a team of competent local professionals who would collaborate on total care of patients they would see again in their practices. Patients could stay closer to their homes for the procedure. Another important benefit of the shared local lab is that pharmaceutical regimens, often a nightmare for such patients, can be coordinated locally.



Retention of qualified specialists in rural areas

Anyone who works in rural health care knows that recruiting and retaining qualified medical specialists is one of the most important and difficult things an administrator does. Many years experience has taught our administrative team to hold out for the best and to support them with appropriate technology. The health status of our population demands that we retain qualified cardiology staff. The numbers support a shared laboratory. We need the knowledge that a highly qualified cardiologist will share with our medical staff. For, their presence affects the entire medical knowledgebase in the community.

Scale of the need supports a decision to move now for this important service.

Halifax Regional Medical Center had mobile cardiac catheterization one day a week in 2005 and until February 2006. Then we lost our invasive cardiologist. We have now recruited another who is Board Certified, trained and experienced in both cardiac and peripheral procedures. We will resume the mobile cardiac catheterization service, but this is expensive and not a permanent solution.

We are ready to care for our community, but cannot even apply to do so unless the 2008 Plan shows a need in Halifax County.

(2) No other fixed or mobile cardiac catheterization service is provided within the same county. "

At 8 hours per day, 52 weeks a year, 240 procedures are 4.6 procedures per day.

ADVERSE EFFECTS ON PROVIDERS AND CONSUMERS OF NOT MAKING THE REQUESTED CHANGE

The only cost-effective way to make cardiac catheterization available full time in Halifax County is to start with a need in the State Medical Facilities Plan. Statute requires a Certificate of Need. There is no fixed cardiac catheterization provider in a 45-minute radius. Patients will be denied access.

A special need determination is necessary because the nature of the State Medical Facilities Plan methodology for shared fixed labs works against successfully justifying a need.

If a rural provider begins to reach 240 procedures and adds a service day or an hour in a day, the methodology ceases to show a need. When a provider does not add a day, the cardiologist gets discouraged and leaves. Patients get frustrated because they have so few scheduling options. This is clearly contrary to the Plan's Basic Principal 2.

> "Expand Health Care Services to the Medically Underserved....to insure access to health care in as equitable a manner as possible..."

If this petition is not granted, we will have no choice but to contract for mobile service. In fact, we would have a better result with the methodology if we contract for less than a full day a week. This does not make sense. Mobile service adds a layer of overhead; the nature of a mobile unit means that we compromise patient privacy and comfort taking patients between the unit and the hospital; and the service gets organized around the vendor schedule, not the patient schedule. We fail to build expertise or equity locally.

The proposed special need adjustment should be considered not as a case of "if," but "when." If this proposal is not approved for inclusion in the 2008 State Medical Facilities Plan, the Halifax/ Northampton community will suffer inconvenience and deferred care for at least two and possibly three more years.

Consider the timetable. Inclusion in the 2008 Plan will result in a CON application approval by 2009 and licensure and certification delay by yet another year. In light of the fact that Halifax has a cardiologist under contract to arrive in September 2007, such a delay is not in the best interest of the patients. Some may get care on a mobile unit, if it is in town on the right day. Some will defer care. Those who elect to travel will spend substantial sums of money just getting to care. As gas costs go up and a 150- mile round trip to Raleigh costs $26 to $30 for

Full lab

Similarly, a dedicated cardiac catheterization laboratory does not make sense for Halifax Regional Medical Center at this time. The level of need in the service area is too small, making the required market share too high to justify the capital cost associated with a dedicated cardiac catheterization laboratory.

Mobile

As an interim step, Halifax Regional Medical Center is returning to the mobile cardiac catheterization laboratory solution. Halifax is in the process of making arrangements with Duke University Medical Center to have a mobile laboratory on site one day a week. Given our past experience and demand from our primary care physicians, we have no doubt that the numbers will reach 240 procedures per 8-hour day per year. If we add a second day, the current wording of the methodology, would be hurting our chances to get a shared lab. A second day would raise the threshold to 480 procedures; again putting need out of reach.

Mobile is at best an interim solution. It demonstrates the need, it shows our referral community that we can safely perform the procedures; it gives us a way to keep our cardiologist.

It is inefficient. It adds overhead. It is always at risk of a truck breakdown and / or damage to the equipment on the road.

CT Angiography

Multi-slice (64) computed tomography is an effective tool in coronary artery disease diagnosis. It reduces the need for diagnostic cardiac catheterization by only five percent. Its primary role is as a substitute for nuclear stress tests. [6]

Shared lab

As noted above, this is the efficient solution for our community. It makes the service available more days a week. It will let us address the entire problem of vascular disease in a single patient. It will not require us to isolate treatment of vascular disease to one part of the body.

[6] Fine, Jeffrey, View Public Comment for Computer Topographic Angiography (CAG-00385N), 6/15/2007

TA 6.57 Computed Tomography Angiography (CTA) for Coronary Artery Disease

Effective Date: Oct 2006 **Revised:** **Next Review:**

Policy: Computed Tomography Angiography (CTA) for coronary artery disease is a new and promising technology, but remains investigational, unproven, and experimental. HPHC will cover on a case by case basis after review by NIA

Process: Reviewed by NIA.

The Technology and the Clinical Circumstances for which it is Being Evaluated:

About 13 million people in the United States have coronary artery disease (CAD). It is the leading cause of death in both men and women. Each year, more than half a million Americans die from CAD. (National Heart. Lung and Blood Institute)

Computed Tomography Angiography (CTA) has been proposed as a noninvasive alternative to invasive coronary angiography. Compared to catheter angiography, which involves placing a sizable catheter and injecting contrast material into a large artery or vein, CTA is a 'noninvasive' outpatient procedure. The procedure for computed tomography angiography (CTA) is to inject a contrast material into a small peripheral vein by using a small needle or catheter to visualize blood flow in arterial and venous vessels throughout the body. The images are generated by a computer synthesis of x-ray transmission data obtained in many different directions in a given plane. Negative findings on CTA obviate invasive angiography, but those with positive CTA findings (i.e., significant stenosis) would still need to be confirmed by invasive coronary angiography. In this case, a high negative predictive value for cardiac CTA would be important.

CTA offers important advantages over conventional angiography, which depicts only the vascular lumen. With CTA, additional information is provided, including vessel wall thickness, relationship to adjacent structures, enhanced depiction of the venous anatomy, and parenchymal information of the target organ and other structures within the scan range and field of view (American College of Radiology, July 2001). The disadvantages of CTA that some studies have shown is that multislice CT exposes the patient to more radiation than single-slice CT and x-ray angiography, and also CTA uses nephrotoxic iodinated contrast material. American Society of Nuclear Cardiology (ASNC) states that the obstacles for routine use of CT angiography are multifactorial and include: 1) substantial movement of the coronary arteries during the cardiac cycle and the limitations of temporal resolution of MDCT technology that involves rapid rotation of heavy collimated detectors; 2) spatial resolution limitations; 3) artifacts caused by overlying calcium or stents that can obscure the presence of luminal narrowing; 4) the need for a slow and regular heart rate during the bolus first-pass acquisition. All of these limitations can reduce the portion of the coronary arterial tree that can be accurately scrutinized and renders this technique, currently, as a research tool. (9)

Supporting Information:

1. Technology Assessment:

Hacker at al conducted Controlled clinical trials to compare conventional coronary angiography to spiral multidetector CT (MDCT) angiography in detection and validation of coronary lesions. They did a retrospective analysis that compared the accuracies of MDCT angiography and myocardial perfusion imaging (MPI) in the detection of hemodynamically relevant lesions of the coronary arteries. Twenty-five patients with suspected or known coronary artery disease were studied. Electrocardiographically gated MPI and 16-MDCT angiography were performed. Ninety-nine coronary vessels were analyzed, and the quality of MDCT angiography images was assessed for 330 coronary segments. Coronary artery diameter was interpretable for 231 (70%) of 330 segments, whereas in 99 (30%) of 330 segments, vessel diameter could not be evaluated because of heavy calcifications, blurring, motion artifacts, or intracoronary stents. MDCT angiography detected stenoses > or = 50% in 15 of 100 coronary arteries. Eight (53%) of 15 stenoses > or = 50% showed reversible or fixed perfusion defects in the corresponding myocardial areas on MPI. Sensitivity, specificity, and negative and positive predictive values were 100%, 87%, 100%, and 29%, respectively, for the ability of MDCT angiography to detect reversible perfusion defects in the corresponding myocardial areas. The authors concluded that compared with MPI alone, CTA added important morphologic information, but **MPI remains mandatory** for evaluating the functional relevance of coronary artery lesions.

- Gaudio C, Mirabelli F, Alessandra L, Nguyen BL, Di Michele S, Corsi F, Tanzilli G, Mancone M, Pannarale G, Francone M, Carbone I, Catalano C, Passariello R, Fedele F. *Noninvasive assessment of coronary artery stenoses by multidetector-row spiral computed tomography: comparison with conventional angiography.* Eur Rev Med Pharmacol Sci. 2005 Jan-Feb;9(1):13-21.

Gaudio et al conducted a clinical trial to analyze the diagnostic accuracy of multi-detector row spiral computed tomography (MDCT) in determining mid- to high-grade coronary artery stenoses (> 50%). Sixty-nine patients with suspected CAD were referred to MDCT coronary angiography and mean values of MDCT coronary narrowings were compared to quantitative coronary angiography. MDCT correctly detected 95 of 123 coronary lesions **(sensitivity 77.2%)** and absence of stenoses was correctly identified in 388 of 426 segments **(specificity 91%).** The sensitivity for the left main (LM), the left anterior descending artery (LAD), the right coronary artery (RCA) and the proximal tract of the circumflex artery (LCX) was 100%, 86.5%, 69.8% and 80% respectively. Classification of patients as having 1-vessel, 2-vessels, 3-vessels or left main disease was accurate in 75.4% (46/61) of patients. The authors concluded that MDCT technology, combined with heart rate control, allows **reliable noninvasive detection of hemodynamically significant CAD.**

- Leber AW, Knez A, von Ziegler F, Becker A, Nikolaou K, Paul S, Wintersperger B, Reiser M, Becker CR, Steinbeck G, Boekstegers P. *Quantification of obstructive and nonobstructive coronary lesions by 64-slice computed tomography: a comparative study with quantitative coronary angiography and intravascular ultrasound.* J Am Coll Cardiol. 2005 Jul 5;46(1):147-54.

Leber and collegues did a clinical trial to determine the diagnostic accuracy of 64-slice computed tomography (CT) to identify and quantify atherosclerotic coronary lesions in comparison with catheter-based angiography and intravascular ultrasound (IVUS). 59 patients were scheduled for coronary angiography due to stable angina pectoris. A contrast-enhanced 64-slice CT was performed before the invasive angiogram. In a subset of 18 patients, IVUS of 32 vessels was part of the catheterization procedure. In 55 of 59 patients, 64-slice CT enabled the visualization of the entire coronary tree with diagnostic image quality (American Heart Association 15-segment model). The overall correlation between the degree of stenosis detected by quantitative coronary angiography compared with 64-slice CT was r = 0.54. **Sensitivity** for the detection of stenosis <50%, stenosis >50%, and stenosis >75% was **79%, 73%, and 80%,** respectively, and **specificity was 97%.** In comparison with IVUS, 46 of 55 (84%) lesions were identified correctly. The mean plaque areas and the percentage of vessel obstruction measured by IVUS and 64-slice CT were 8.1 mm2 versus 7.3 mm2 ($p < 0.03$, $r = 0.73$) and 50.4% versus 41.1% ($p < 0.001$, $r = 0.61$), respectively. Leber et al concluded that Contrast-enhanced 64-slice CT is a **clinically robust modality** that allows the identification of proximal coronary lesions with excellent accuracy. Measurements of plaque and lumen areas derived by CT

- *Unicare:* (April 2005):
  Computed tomography angiography is considered **investigational/not medically necessary** for the evaluation of coronary arteries, including, but not limited to the following:
    - Screening for coronary artery disease (CAD), either in asymptomatic subjects or as part of a preoperative evaluation
    - Diagnosis of CAD, in patients with acute or non-acute symptoms, or after a coronary intervention
    - Delineation of a coronary artery anatomy or anomaly

  http://medpolicy.unicare.com/policies/RAD/CTA.html

3. Governmental/Regulatory Agencies:
   - *FDA:* Multiple manufacturers have received FDA 510(k) clearance to market MDCT machines equipped with at least 16 detector rows and at least two models of EBCT machines have been cleared through FDA 510(k) clearance. Intravenous iodinated contrast agents used for CTA have also received FDA approval. (7)

   - *CMS:* No national coverage policy specifically addressing CTA for coronary artery evaluation was found. CMS has issued a National Coverage Determination regarding CT scanning in general. This policy states that diagnostic examinations of the head and other parts of the body performed by CT scanners are covered if the medical and scientific literature and opinion support the effective use of a scan for the condition, and the scan is: reasonable and necessary for the individual patient; and performed on a model of CT equipment that has been approved by the FDA. (5)

   - *National Heritage Insurance company (Northeast CMS):* March 2006 (6)

     Indications of Coverage:
     The MDCT angiography of the heart may be employed in a variety of clinical settings:
     1. Facilitation of the diagnostic cardiac evaluation of a patient with chest pain syndrome (e.g. chest pains, anginal equivalent, angina). Depending on the clinical presentation, the MDCT for coronary artery evaluation may precede a perfusion stress test, or it may be used to clarify a perfusion stress test that is non-diagnostic, equivocal, or is inadequate in explaining the patient's symptoms.
     2. Facilitation of the management decision of a symptomatic patient with known coronary artery disease. (eg., post-stent, post CABG) when the results of the MDCT may guide the decision for repeat invasive intervention.
     3. Assessment of suspected congenital anomalies of coronary circulation or great vessels.
     4. Assessment of the symptomatic patient when presentation is suspicious of aortic dissection.
     5. Facilitation of diagnostic evaluation and management of an asymptomatic patient at high cardiovascular risk (e.g.
     newly diagnosed severe left ventricular systolic dysfunction of unknown etiology).
     6. Assessment of coronary artery anatomy prior to non-coronary cardiac surgery (e.g. valve repair or replacement, ascending aortic aneurysm or dissection repair).
     7. Facilitation of diagnostic evaluation and management of patients with implantable cardiac devices (pacemakers, ICDs) who are about to undergo, or have undergone therapeutic electrophysiological procedures, in which detailed anatomical knowledge of the atria, pulmonary veins, and cardiac veins is required.

     Limitations of Coverage:
     1. The test is never covered for screening, i.e., in the absence of signs, symptoms of disease.
     2. The selection of the test should be made within the context of other testing modalities so that the resulting information facilitates the management decision, not merely adds a new layer of testing.
     3. Coverage of this modality for coronary artery assessment is limited to devices that process thin, high resolution slices (1 mm or less). The multidetector scanner must have at least 16 slices per second capability.
     4. The administration of beta blockers and the monitoring of the patient by a cardiologist during the MDCT are not separately payable services.
     5. All studies must be ordered by a physician or a qualified non-physician practitioner.

10) Hoffmann MH, Shi H, Schmitz BL, Schmid FT, Lieberknecht M, Schulze R, Ludwig B, Kroschel U, Jahnke N, Haerer W, Brambs HJ, Aschoff AJ. *Noninvasive coronary angiography with multislice computed tomography.* JAMA. 2005 May 25;293(20):2471-8.
11) Hacker M, Jakobs T, Matthiesen F, Vollmar C, Nikolaou K, Becker C, Knez A, Pfluger T, Reiser M, Hahn K, Tiling R. *Comparison of spiral multidetector CT angiography and myocardial perfusion imaging in the noninvasive detection of functionally relevant coronary artery lesions: first clinical experiences.* J Nucl Med. 2005 Aug;46(8):1294-300.
12) Gaudio C, Mirabelli F, Alessandra L, Nguyen BL, Di Michele S, Corsi F, Tanzilli G, Mancone M, Pannarale G, Francone M, Carbone I, Catalano C, Passariello R, Fedele F. *Noninvasive assessment of coronary artery stenoses by multidetector-row spiral computed tomography: comparison with conventional angiography.* Eur Rev Med Pharmacol Sci. 2005 Jan-Feb;9(1):13-21.
13) Leber AW, Knez A, von Ziegler F, Becker A, Nikolaou K, Paul S, Wintersperger B, Reiser M, Becker CR, Steinbeck G, Boekstegers P. *Quantification of obstructive and nonobstructive coronary lesions by 64-slice computed tomography: a comparative study with quantitative coronary angiography and intravascular ultrasound.* J Am Coll Cardiol. 2005 Jul 5;46(1):147-54.
14) ACCF/ACR/SCCT/SCMR/ASNC/NASCI/SCAI/SIR 2006 Appropriateness Criteria for Cardiac Computed Tomography and Cardiac Magnetic Resonance Imaging. Journal of the American College of Cardiology Vol. 48, No. 7, 2006. http://www.acc.org/qualityandscience/clinical/pdfs/CCT.CMR.pdf

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Rec'd @ July 24 2007 Greenville Public Hearing

Public Hearing Comments on Proposed 2008 State Medical Facilities Plan
Cardiac Catheterization

July 24, 2008, 1:30 PM

Pitt County Office building

Greenville, NC

Presented by
William Mahone,
President and CEO
Halifax Regional Medical Center

My name is William Mahone, and I am President and CEO of Halifax Regional Medical Center, in Roanoke Rapids and I am here today on behalf of the many people in Halifax and Northampton Counties. We're very proud of our 206-bed Medical Center, our Medical Staff and their services, and we work with limited resources to provide the best and most accessible health care to the 158,000 residents in our service area.

My colleague, Michael Joyner, and I traveled here today to emphasize the importance of our message regarding a proposed special need determination for a shared fixed cardiac catheterization laboratory in Halifax County. I assume you know of our location. Roanoke Rapids is an hour north of Rocky Mount on I-95, near the Virginia border. Our communities are struggling with the economic shift out of textiles and into the next new industry. Meanwhile we've had years of farm work, manufacturing, and low income jobs that have given us a legacy of chronic diseases. On the coastal plain, like parts of the mountains, we have people who live on dirt roads, in homes without electricity. Heart disease rates are 50 percent above the state average and we rank number two in poverty.

Our service area is very rural. While more urban residents become accustomed to driving on interstates, these are intimidating to the patients in our rural areas. We have documented cases of patients who had third party coverage and who refused to travel to Raleigh to get cardiac catheterization recommended by their physicians. In 2006 we had four patients who failed their diagnostic cardiac caths and refused to travel to Raleigh for

We are not asking for an exception. We are asking that the State Health Coordinating Council permit us to make better use of an existing resource. We have applied for equipment to improve peripheral angiography diagnosis and treatment at the hospital and have demonstrated that that investment can pay for itself. With only a small additional investment, we can expand the equipment's capacity and use it for cardiac catheterization. But to do so, we will need Certificate of Need approval, and that approval requires the need be identified in the State Medical Facilities Plan. The shared fixed laboratory offers a very efficient way to serve rural patients.

Halifax Regional Medical Center has demonstrated that it can provide cardiac catheterization safely. With the mobile service we reached days when our cardiologist did six to eight procedures. The threshold for a shared fixed lab is only 4.6 procedures a day (240/52). Help us maintain our momentum.

We considered alternatives such as waiting another year. But when we considered the impact of waiting, the delay was unacceptable. Even with a need listed in the 2008 Plan, it will be 2010 before we could apply and receive Certificate of Need approved. We are serving a population that has already waited too long. They have advanced cardiac disease. Please do not delay another year our ability to make these services available to our patients. Our quality systems are in place and our staff is trained. We have recruited an exceptional physician and have arranged the required back up. Making us wait only increases the overhead we pay to a mobile provider and restricts the service to one day a week. Cardiac catheterization rates have been steadily increasing in North Carolina, about 2 percent a year for the past seven years. Permitting us to do a limited number of procedures at Halifax Memorial Hospital will not hurt any of the existing programs. Increases in use rate, and population will more than offset any procedures that might remain in Halifax rather than travel outside.

Public Hearing Comments on Proposed 2008 State Medical Facilities Plan
Cardiac Catheterization

August 1, 2007, 1:30 PM

Jane S. McKimmon Center

Raleigh, NC

Presented by
Diane Barlow
Vice-President
Halifax Regional Medical Center

My name is Diane Barlow, and I am Vice-President of Halifax Regional Medical Center, in Roanoke Rapids. I am here today on behalf of the many people in Halifax and Northampton Counties. We are very proud of our 206-bed Medical Center, our Medical Staff and their services, and we work with limited resources to provide the best and most accessible health care to the 158,000 residents in our service area.

My colleague, Karen Daniels, and I traveled here today to emphasize the importance of our message regarding a proposed special need determination for a shared fixed cardiac catheterization laboratory in Halifax County. Roanoke Rapids is an hour north of Rocky Mount on I-95, near the Virginia border. Our communities are struggling with the economic shift out of textiles and into the next new industry. Meanwhile we've had years of farm work, manufacturing, and low income jobs that have given us a legacy of chronic diseases. On the coastal plain, like parts of the mountains, we have people who live on dirt roads and in homes without electricity. Heart disease rates are 50 percent above the state average and we rank number two in poverty.

Our service area is very rural. While more urban residents become accustomed to driving on interstates, these are intimidating to the patients in our rural areas. We have documented cases of patients who had third party coverage and who refused to travel to Raleigh to get cardiac catheterization recommended by their physicians. In 2006 we had four patients who failed their diagnostic cardiac caths and refused to travel to Raleigh for

needed care. Barriers are many including travel, transportation, drivers and their availability to drive and wait for services of others. Health literacy, i.e. reading and understanding instructions, is a problem for many in our area.

In 2005, we developed a cardiac catheterization program using a mobile unit from MedCath. We had clinical back up from WakeMed and Pitt County Memorial Hospital. The number of catheterizations climbed quickly and we were well on our way to reaching the threshold that would qualify the county for a shared fixed lab this year, when our cardiologist left the area. We have recruited a new cardiologist, Dr. Geloo, and have done some things organizationally to assure that he will stay – and you can help us with that important goal. The mobile cardiac catheterization service will start up again in September. This time Duke will be the vendor. Back up arrangements will be the same.

We have recently strengthened our Management Team and are resolved to provide the services most needed by our community. With almost 2,000 cardiac catheterizations in our service area every year, it will take only a 12 percent market share to sustain a strong shared fixed cardiac catheterization laboratory. More importantly, offering both cardiac and peripheral vascular angiography in Roanoke Rapids will permit our medical staff to treat the whole patient in their home community. Ms. Daniels will address more clinical issues.

I understand the role of the State Planning process in containing costs and minimizing duplication. But it is equally important to consider the second basic plan principle, - improving access. North Carolina's urban centers: Charlotte, Asheville and Raleigh are growing very rapidly. They share the same climate as the state's rural communities, but have many more medical resources. We can do a better job of sustained growth in North Carolina if we think about spreading resources in a way that makes the outlying communities attractive. Rural communities have attractions, in our case Lake Gaston, and we have retirement communities. To support these and long time residents, we need the technology to make our medical support system attractive to physicians, nurses and health care technologists.

We are not asking for an exception. We are asking that the State Health Coordinating Council permit us to make better use of an existing resource. We have applied for equipment to improve peripheral angiography diagnosis and treatment at the hospital and have demonstrated that that investment can pay for itself. With only a small additional investment, we can expand the equipment's capacity and use it for cardiac catheterization. But to do so, we will need Certificate of Need approval, and that approval requires the need be identified in the State Medical Facilities Plan. The shared fixed laboratory offers a very efficient way to serve rural patients.

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Anyone who has worked with a mobile service knows the drawbacks. Trucks will break down, equipment is jostled and most importantly, the equipment is not there when the patients most need it.

I also want to comment on the State Plan's methodology for calculating need for a unit of shared fixed cardiac catheterization equipment as it is imperfect. The methodology sets a moving target based on the number of 8-hour days of mobile service we have. If we have one day of service a week, the target is 240 procedures. If we add a second 8-hour day, or an additional hour to an existing day, the target moves up 240 procedures a year for each eight hours of service per week. This is not accurate or fair. We ask that you be accurate and fair and give us a chance to make efficient use of our resources.

We will be submitting a formal petition later this summer.

Now, I would like to introduce our Vice-President of Nursing, Karen Daniels.

Public Hearing Comments on Proposed 2008 State Medical Facilities Plan
Cardiac Catheterization

August 1, 2007, 1:30 PM

Jane S. McKimmon Center

Raleigh, NC

Presented by
Karen Daniels, RN,
Vice President and CNO
Halifax Regional Medical Center

Good afternoon, my Name is Karen Daniels. I am a registered Nurse with 27 years of experience and Vice President of Nursing Services at Halifax Regional. I have had the great good fortune of being a military wife and have practiced my profession all over the world. As a nurse specializing in critical and emergency care, I have first hand knowledge of the devastation caused by vascular disease including heart attack, stroke, as well as loss of limb. I have also seen how often it is under treated particularly in rural communities such as ours.

Halifax Regional will be working closely with an interventional cardiologist who also has received training in cardiac and vascular disease in eastern North Carolina. Dr. Geloo's training in both coronary and peripheral vascular disease will offer a new and unique perspective to Roanoke Rapids and the population within the surrounding communities.

Atherosclerosis is a systemic disease that leads to devastating acute and long term consequences. While the disease can affect multiple vascular beds including the heart, kidneys, legs, and brain, the disease process is exactly the same in these varied areas. Most patients with vascular disease manifest their disease in multiple vascular beds; therefore such patients may go to a cardiologist for coronary disease, a neurologist for carotid artery disease, and a vascular surgeon for leg pain as a result of poor circulation. This approach may delay global diagnosis and more importantly perhaps, disease modifying treatment. Increased awareness of disease in one vascular bed leads to early diagnosis of the disease manifestation in another vascular bed. Dr. Geloos' unique training will afford us the opportunity to focus on the disease and the patient as a whole rather than focusing on individual processes.

This approach to disease management is an important one in that all of these diseases are interrelated. A patient with poor circulation to the lower extremities is at an increased risk for heart attack and death; conversely a patient with coronary disease is at significant risk for stroke. These relationships are well documented by research and epidemiology trials. In many cases these disease states will require invasive angiography for definitive diagnosis.

Approval of an angiography suite and cardiac catheterization laboratory at Halifax Regional will provide leading edge technology for diagnosis and potentially definitive treatment, services currently unavailable for our patients. As a result of his training Dr. Geloo will be able to offer patients on-site revascularization for arterial insufficiency in select patients for whom such procedures can be performed safely. Complex patients will continue to be referred to tertiary care facilities. Peripheral arterial disease is routinely under-diagnosed and it is our belief that neighboring tertiary facilities will see an increase in the number of referrals from Halifax as a result of our expanded focus on atherosclerosis.

Cardiac catheterization will be a very important addition to the services we provide at Halifax Regional. Approximately one third of all patients undergoing diagnostic angiography actually undergo angioplasty or stenting during the same procedure. Therefore the majority of these patients undergo only the diagnostic procedure.
In 2005 and until April 2006, Halifax Regional Medical Center had mobile cardiac catheterization one day a week. The program was well accepted by the community and referring physicians and the number of procedures grew rapidly. Our patients reflected the national predictions and we were very safe and successful in providing the service. Last year, 734 people from Halifax and Northampton Counties went elsewhere for diagnostic catheterizations. This is two people a day -- more than enough to support a shared fixed cardiac catheterization

We have documented evidence that requiring travel outside the service area automatically deters a substantial proportion of our residents from follow up on treatment or diagnostic recommendations. Patient reasons for deferral involve their perception of distance from home to the treatment center, fear of travel on the interstate and urban beltways, and distance of the referral center from family and support networks. We cannot address their concerns for every specialized service. However, the shared cardiac catheterization laboratory is uniquely suited to address care in a small market. The same disease that causes cardiac circulatory problems causes peripheral circulatory problems. The tool for finding and treating both is the same equipment.

The advent of multi-slice computed tomography (CT) introduced coronary artery CT as a diagnostic alternative. However, by current indications, the new modality is truly an adjunct, not a replacement for cardiac catheterization. CT cannot provide sufficient specificity for a definitive treatment plan. According to a May 2007 article written by the founding members of the Society for Cardiovascular Computed Tomography, David Allie, MD, et al "angiography is most valuable for identifying risk in an asymptomatic population."

Our lab would first have to establish a long record of safety with excellent clinical outcomes before consideration of more urgent procedures. That being said we believe the availability of angiography in our community will increase the awareness of the life-threatening consequences of atherosclerosis and it is our hope this will lead to an increased awareness, recognition and diagnosis and more importantly definitive care.

Often, patients who choose to live in rural communities such as ours feel they make this decision at the expense of healthcare. Patients in rural communities should have the same access to leading edge healthcare technologies as those living in larger metropolitan areas. An angiographic suite and cardiac catheterization laboratory will assist us in taking great strides toward achieving this goal.

HALIFAX REGIONAL MEDICAL CENTER

Good afternoon, my name is Michael Joyner and I am a Registered Nurse and manager of cardiac services for the nursing division at Halifax Regional. Having worked almost exclusively in northeastern North Carolina for 25 years, I have firsthand knowledge of the extent vascular disease affects our rural communities.

Halifax Regional will be working closely with an interventional cardiologist who also has received training in cardiac and vascular disease in eastern North Carolina. Dr. Geloo's training in both coronary and peripheral vascular disease will offer a new and unique perspective to Roanoke Rapids and the population within the surrounding communities.

Atherosclerosis is a systemic disease that can lead to devastating acute and long term consequences and is consistently among our top 10 DRGs for hospital admission. Dr. Geloos' unique training will afford us the opportunity to focus on the disease and the patient as a whole rather than focusing on individual processes.

This approach to disease management is an important one in that all of these diseases are interrelated. A patient with poor circulation to the lower extremities is at an increased risk for heart attack and death; conversely a patient with coronary disease is at significant risk for stroke. These relationships are well documented by research and epidemiology trials. In many cases these disease states will require invasive angiography for definitive diagnosis.

Approval of an angiography suite and cardiac catheterization laboratory at Halifax Regional will provide leading edge technology for diagnosis and potentially definitive treatment, services currently unavailable for our patients. As a result of his training Dr. Geloo will be able to offer patients on-site revascularization for arterial insufficiency in select patients for whom such procedures can be performed safely. Complex patients will continue to be referred to tertiary care facilities.
Peripheral arterial disease is routinely under-diagnosed and it is our belief that neighboring tertiary facilities will see an increase in the number of referrals from Halifax as a result of our expanded focus on atherosclerosis. This alone will substantially advance Halifax Regional's capability to serve

Greensboro PH
7-20-07
Cardiac Cath
Tom

Good afternoon, my name is Michael Joyner and I am a Registered Nurse and manager of cardiac services for the nursing division at Halifax Regional. Having worked almost exclusively in northeastern North Carolina for 25 years, I have firsthand knowledge of the extent vascular disease affects our rural communities.

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Atherosclerosis is a systemic disease that can lead to devastating acute and long term consequences and is consistently among our top 10 DRGs for hospital admission. While the disease can affect multiple vascular beds including the heart, kidneys, legs, and brain, the disease process is exactly the same in these varied areas. Most patients with vascular disease manifest their disease in multiple vascular beds; therefore such patients may go to a cardiologist for coronary disease, a neurologist for carotid artery disease, and a vascular surgeon for leg pain as a result of poor circulation. This approach may delay diagnosis and more importantly perhaps, disease modifying treatment. Increased awareness of disease in one vascular bed leads to early diagnosis of the disease manifestation in another vascular bed. Dr. Geloos' unique training will afford us the opportunity to focus on the disease and the patient as a whole rather than focusing on individual processes.

This approach to disease management is an important one in that all of these diseases are interrelated. A patient with poor circulation to the lower extremities is at an increased risk for heart attack and death; conversely a patient with coronary disease is at significant risk for stroke. These relationships are well documented by research and epidemiology trials. In many cases these disease states will require invasive angiography for definitive diagnosis.

Approval of an angiography suite and cardiac catheterization laboratory at Halifax Regional will provide leading edge technology for diagnosis and potentially definitive treatment, services currently unavailable for our patients. As a result of his training Dr. Geloo will be able to offer patients on-site revascularization for arterial insufficiency in select patients for whom such procedures can be performed safely. Complex patients will continue to be referred to tertiary care facilities.

Supplemental Information for Petitions filed by Halifax Regional Medical Center and Scotland Memorial Hospital for Special Need Determination for Shared Fixed Cardiac Catheterization Laboratories in Halifax and Scotland Counties.

Petitioner 1:
Halifax Regional Medical Center
250 Smith Church Road
Roanoke Rapids, NC 27870

Petitioner 2:
Scotland Memorial Hospital
500 Lauchwood Drive
Laurinburg, NC 28352

Contact 1:
William Mahone, V
President
Halifax Regional Medical Center
250 Smith Church Road
Roanoke Rapids, NC 27870
(252) 535-8011

Contact 2:
Gregory C. Wood
President and CEO
Scotland Memorial Hospital
500 Lauchwood Drive
Laurinburg, NC 28352
Ph: 910-291-7501

The following information provided by Phillips shows the contents of a "cardiac package" that can be acquired and installed on an angiography laboratory to render it capable of producing high quality cardiac catheterization. Note that the angiography laboratory camera is designed with a wide field needed to view a peripheral vascular bed. The cardiac package provides hardware and software to narrow the camera aperture and increase the shutter speed to handle the requirements of a beating heart. The estimated cost of a package like this is approximately $200,000. Thus, the adaptation costs of a shared lab make this a highly cost effective solution for a rural area.

By contrast, typically a cardiac catheterization laboratory has only the narrow aperture camera. The current MedCath laboratories are narrow aperture labs.

1 ****NNAE085 Allura Xper FD20 Card Sys 1**

The Allura Xper FD20 Cardiac single plane cardiovascular system is comprised of a ceiling mounted stand and digital imaging X-ray system for cardiovascular diagnostic and interventional procedures

The Allura Xper FD20 system uses an integrated single-host concept. The system is comprised of five functional building blocks: Geometry, X-ray Generation, User Interface, Image Detection, and Viewing. Each functional building block is explained in further detail.

Xres Cardiac (NCVA664)

- Xres Cardiac enhances sharpness, contrast, and reduces noise in fluoroscopy and exposure runs for cardiac studies

4	**NCVA118	**Ventricular Quantification SW Pkg (Xper)**	1	$12,060.00	$12,060.00

Calculates the Ejection Fraction and local Wall Motion parameters in different formats. Functions include: Various LV-volumes Ejection Fraction Cardiac Output Centerline Wall Motion Slager Wall Motion Regional Wall Motion Calibration routines

5	**NCVA119	**Coronary Quantification SW Pkg (Xper)**	1	$5,695.00	$5,695.00

Functions include:
- Diameter measurement along the selected segment;
- Densiometric information;
- Cross sectional area;
- percent stenosis;
- Pressure gradient values;
- Stenotic flow reserve;
- Calibration routines

6	**NCVA121	**FULL AUTOCAL**	1	$5,360.00	$5,360.00

The AutoCal option is a software package to be used in conjunction with quantitative analysis software packages. It provides an auto calibration procedure for an object to be analyzed that is placed in the iso-center. When the object to be analyzed (e.g. Left Ventricle Vessel Segment) is placed in the iso-center AutoCal avoids the need to:
- acquire an additional image series containing a sphere or grid for calibration purposes
- calibrate manually on a calibration object (e.g. catheter) displayed in the image or image series to be analyzed

7	**NCVA660	**3D-RA R.5**	1	$51,925.00	$51,925.00

Allura 3D-RA is designed to provide three dimensional images of brain and peripheral vessels

Image Acquisition
Image acquisition is performed with the Rotational Angiography feature of the Allura Xper FD series with the flexibility to position the C-arm in either head or side position

- C-arm in Head position: the Rotational Angiography run is performed over a scan range of 240 degrees with a rotation speed up to 55 degrees/sec

10	**NCVA116	**3D RA Control for Xper Module**	1	$10,720.00	$10,720.00

Table Side Module functionality for Allura Xper FD20 used with Integris 3D-RA Release 4.2.
For further improvement of interventional procedures efficiency the following workflow enhancers are made available in the examination room: With the Xper touchscreen module the physician has all 3D functionality needed at tableside. Functionality like rotating panning zooming AVA Virtual stinting 3 and 3D Follow C-arc can be perfomed. No need for the Physician to leave the examination room. 3D Automatic Position Control (3D-APC), when the optimal working position has been chosen via the Integris 3D-RA interventional tool the C-arc will automatically steer to this position 3D Follow C-arc: When the position of the C-arc (not using any X-ray) is changed the 3D volume will automatically follow the position of the C-arc. This means the position of the C-arc (and therefore the 2D projection) and the 3D volume are always aligned.

13	**NCVA675	3D Roadmapping	1	$52,260.00	$52,260.00

This extends the capabilities of the integrated 3D product by providing a sustainable 3D roadmap to support interventional procedures.

The 3D Roadmap option matches the real-time 2D fluoro images with the 3D reconstruction of the vessel tree. So one can see the advancement of the guide wire, catheter and coils on the 3D volume in real time.

The 3D roadmap will remain if one changes the C-arm position, the SID and/or the Field of View of the flat detector. The 3D volume will follow automatically the orientation of the C-arc, providing the flexibility to chose the optimal position of the C-arc.

Top of Document

Technology and Equipment Committee Meeting

August 29, 2007

CARDIAC CATHETERIZATION MATERIAL

Material Related to

Petition-2: Scotland Memorial

SCOTLAND
MEMORIAL HOSPITAL

August 1, 2007

DFS Health Planning
RECEIVED

AUG 02 2007

Medical Facilities
Planning Section

From: Gregory C. Wood, President and CEO
Scotland Memorial Hospital
500 Lauchwood Drive
Laurinburg, NC 28352
Ph: 910-291-7501

To: State Health Coordinating Council, and
Medical Facilities Planning Section
Division of Facility Services
2714 Mail Service Center
Raleigh, North Carolina 27699-2714

Re: **PETITION**: Scotland Memorial Hospital; Requests adjustment in the Shared Fixed Cardiac Catheterization Equipment Need Determination for Scotland County as set forth on page 153 in the *Proposed 2008 State Medical Facilities Plan (SMFP)* to identify a need for one unit of shared fixed cardiac catheterization equipment in Scotland County.

Petition

By this petition, Scotland Memorial Hospital (SMH) requests that the Medical Facilities Planning Section adjust the *Proposed 2008 SMFP* to show a specific need for one unit of shared fixed cardiac catheterization equipment in Scotland County. Table 9Y on Page 153 would reflect these changes:

Hospital Service System	Shared Fixed Cardiac Catheterization Equipment Need Determination	Certificate of Need Application Due Date	Certificate of Need Beginning Review Date
Scotland	1	April 15, 2008	May 1, 2008

Scotland Memorial reported performing 427 mobile cardiac catheterizations in 2006.[1] This number is just 20 procedures shy of reaching the threshold to justify a unit.

Hours per Day	Days per Week	Total Hours per Week	per "8-hour Day" per Week	SMH Threshold	SMH 2007 HLRA Reported	Threshold # Variance	Threshold % Variance
7.45	2	14.90	240	447	427	20	4.7%

The methodology works against success in reaching the required threshold. As volume builds, scheduling demands push administration to add more time on the mobile unit. With each added day, the methodology sets a higher threshold, keeping success just outside the host site's reach. Scotland Memorial Hospital, in fact, surpassed the 240 procedure threshold for one day in 2003 and was forced to add another day to provide its service area patients with adequate access to quality cardiac care. Once again, Scotland Memorial is close to the threshold and offering good access to patients suggests adding a day, but if another day of mobile service is added, the threshold will be pushed further out of reach.

As part of its community mission, Scotland Memorial Hospital must strive to develop its cardiac care program. Its service area patients need and deserve a more fully developed cardiac care program close to home.

Cardiac catheterization is a key element in a cardiac care program because it is the definitive tool for diagnosis and management of coronary artery disease. Cardiac catheterization is among the top five hospital procedures performed on males, according to the Agency for Healthcare Research and Quality. The cardiac catheterization rate for all hospitalized patients nationwide was 6.2 per 1000.[2] Increasingly, cardiac catheterization is an outpatient procedure, and those procedures are not reflected in the numbers above.

The advent of 64-slice computed tomography made it possible to capture images of coronary arteries non-invasively (CTA). CTA is a diagnostic alternative primarily valuable for ruling out coronary artery blockage as a cause of cardiac problems.[3] Cardiac CT has the potential to become a complementary tool to invasive coronary catheterization.[4] However, a technology assessment, TA 6.57 Computed Tomography Angiography (CTA) for Coronary Artery Disease, performed in October 2006 by Harvard Pilgrim HealthCare resulted in the following policy: "Computed Tomography Angiography (CTA) for coronary artery disease is a new and promising technology, but remains investigational, unproven, and experimental. HPHC will cover on a case by case

[1] 2007 Hospital License Renewal Application
[2] Advance Data from Vital and Health Statistics No. 385, July 12, 2007, Center for Disease Control
[3] Health Imaging and IT, July 2007, pg 40
[4] http://www.cathlabdigest.com/article /962, Research Show New CT Can Help Physicians Diagnose Heart Disease in Early Stages, pg 4.

Prevention of Out Migration

Scotland Memorial's residents choose to stay in Scotland County for their healthcare when possible. For its full time services, Scotland Memorial enjoys more than 70 percent average market share of Scotland County residents. This reflects both its positive reputation and, **more importantly,** the reliance and dependency the community has on Scotland Memorial to meet its healthcare needs.

Given the frequency of demand for cardiac procedures – of procedures performed on males in hospitals, one in four is a cardiac procedure;[7] it is unreasonable to ask residents of Scotland Memorial Hospital's service area to travel an hour or more for this critical diagnostic procedure. For many, the time involved means a delay of hours or, more likely, days to get appropriate treatment. Time involved in stabilizing the patient, determining the diagnosis, arranging medical transport, coordinating care teams at the referral hospital adds up to critical time lost for the patient for whom timely cardiac catheterization is the best solution.

Scotland Memorial Hospital has mobile cardiac catheterization service available two days a week. The program has been well accepted by the community and referring physicians and the number of procedures has grown. However, with the service unavailable five days a week, many patients are referred elsewhere because time is critical to optimal care. Today, our physicians and emergency department refer more than ten percent of our cardiac catheterization patients to Pinehurst, UNC Chapel Hill, and Duke because of mobile service unavailability. However, many patients refuse to make that trip regardless of the exceptional quality available at these centers. For many patients, travel and cost are the ultimate barriers to care. Cardiac catheterization service needs to be available to Scotland Memorial patients on a full-time basis. A shared fixed laboratory would permit that.

Future Demand

Summary

Most Scotland County residents live 45 minutes to two hours away from the nearest cardiac catheterization equipment. The nearest providers are in Pinehurst and Lumberton, each approximately 45 minutes from Scotland Memorial Hospital; the Raleigh/Durham area providers are as much as two hours away. The cardiac service area for Scotland Memorial Hospital includes five counties: Scotland, Robeson, Hoke and Richmond Counties in North Carolina and Marlboro County in South Carolina and consists of approximately 289,000 people in 2007. The projected population of the service area is shown below.

[7] Advance Data from Vital and Health Statistics No. 385, July 12, 2007, Center for Disease Control

Health Status

According to the NC State Center for Health Statistics, Scotland Memorial's North Carolina service area resident death rates are much higher than the State average. In 2005, heart disease represented 236 deaths per 100,000 Scotland County residents compared to the state's rate of 204.

Heart Disease Death Statistics

Geographical Area	Number of Deaths 2005	Death Rate 2005	Number of Deaths 2001-2005	Death Rate 2001-2005	Age-Adjusted Death Rate 2001-2005
Scotland	87	236.2	471	260.5	275.5
Robeson	285	223.2	1548	245.9	306.0
Richmond	137	293.5	836	358.7	338.7
Hoke	57	140.1	301	160.8	269.8
North Carolina	17,681	203.6	91,056	215.9	226.8
Percent of State					
Scotland		116%		121%	121%
Robeson		110%		114%	135%
Richmond		144%		166%	149%
Hoke		69%		74%	119%

Source: http://www.schs.state.nc.us/SCHS/deaths/lcd/2005/heartdisease.html

Data on South Carolina mortality rates indicate that heart disease is by far the leading cause of death among Marlboro County residents with a comparatively high rate of 409 deaths per 100,000 population.[9]

Cardiac Catheterization Utilization Rates

Cardiac catheterization, statewide, has experienced a steady increase for the past seven years. In 2006, there were 10.5 cardiac catheterizations per 1000 residents. The rate is trending towards 10.8 per 1,000 by 2009. Following this trend, Scotland Memorial Hospital needs only 15 percent market share of its service area to perform 500 cardiac catheterizations by 2010. In fact, our acute market share suggests that share would be even higher than 15 percent.

[9] http://www.scdhec.gov/hs/epidata/reports/county_reports/mor/marlboro.pdf

No Unnecessary Duplication of Services

Scotland Memorial Hospital refers its cardiac care patients to Pinehurst, UNC and Duke. Pinehurst is 30 miles away and UNC and Duke are closer to 100 miles away for residents of Scotland's service area. FirstHealth performed nearly 3,500 cardiac catheterization and UNC and Duke together did more than 8,900. The additional number of cardiac catheterizations that will be done in Scotland County in lieu of FirstHealth, UNC or Duke will not be enough to make a difference in the viability of any of these programs. With better diagnostic capacity, Scotland's referrals to the specialty centers will likely increase. In fact, our mobile cardiac catheterization vendor and the hospital that receives most of our referrals for scheduling overflow and more specialized procedures, FirstHealth Moore Regional Hospital, is in full support of Scotland Memorial's petition. See Attachment C.

Alternatives

Status quo

With almost 3,000 residents of the Scotland Memorial Hospital service area needing cardiac catheterizations and 4,000 needing peripheral angiography, maintaining the status quo is not serving the population well.

Today, patients are treated in a space that is physically outside the hospital. Patients would avoid exposure to the elements in the trek between hospital and mobile unit, if we have a fixed unit. The service is not available every day; but patients get sick every day.

Status quo is not acceptable.

Mobile

Scotland Memorial Hospital will continue to offer mobile cardiac catheterization services as it has for more than fifteen years, but mobile service is only an interim solution. Though FirstHealth Moore Regional provides Scotland with quality equipment, mobile service is inefficient, adds overhead and is always at risk of a truck breakdown and / or damage to the equipment on the road. It can also compromise patient privacy with transport to and from the mobile unit.

Our successful mobile cardiac catheterization experience and demand for the service from our cardiologists and primary care physicians demonstrates our need and shows we can sustain the service.

Scotland Memorial has surpassed the threshold and added additional mobile time and will continue the less desirable mobile service. Ultimately, the only way for Scotland Memorial to sustain the threshold is holding down mobile days to force the fit, if necessary. If this proposal is not approved for inclusion in the 2008 State Medical Facilities Plan, the Scotland community will suffer through additional years of waiting to get the same advantage of a locally available cardiac catheterization service. A full-time cardiac catheterization service at Scotland Memorial will allow treatment of cardiac disease early with good results preventing the disease's progression to a later stage where patients require more drastic intervention.

Scotland Memorial has demonstrated success with the services it offers. Scotland has highly qualified, experienced physicians and staff in place to offer the service. Delaying Scotland Memorial patients' access to full-time cardiac catheterization service denies them access to quality cardiac care that could be provided successfully and cost effectively at home.

Conclusion

Scotland Memorial Hospital has the cardiologists, physicians and staff to support a full-time shared fixed cardiac catheterization service. It has demonstrated that it can sustain the volume of cardiac catheterizations needed to support the service. It has demonstrated that other area providers will not be adversely affected by the service. The service area has a high incidence of cardiac disease, and more than enough demand to support the service. Patients will benefit from the addition of a special need for a shared fixed cardiac catheterization laboratory in Scotland County in the 2008 State Medical Facilities Plan.

Attachments:

A. Harvard Pilgrim HealthCare Technology Assessment Policy
B. Centers for Medicare & Medicaid Article with excerpt from National Clearinghouse Guideline
C. FirstHealth Moore Regional Support Letter
D. Centers for Medicare & Medicaid Comment for Computer Tomographic Angiography

- *Technology Evaluation Center (TEC): Contrast-Enhanced Cardiac Computed Tomographic Angiography* in the Diagnosis of Coronary Artery Stenosis or for Evaluation of Acute Chest Pain, Volume 21, No. 5, August 2006.

  The studies evaluating the use of CTA in comparison to angiography are relatively small studies from single centers. Their major failing is that they enrolled convenience samples of patients being referred for angiography. The results from these studies may not generalize to lower-risk populations. In addition, such studies only directly address the question of whether CTA can accurately triage patients already referred for angiography. The use of CTA as part of the initial workup of chest pain or possible angina is not addressed at all in these kinds of studies. Clinical trials comparing patients undergoing CTA as part of their diagnostic workup compared to patients not undergoing CTA may be required to demonstrate improved patient outcomes. There is **no evidence** except in the ER regarding the use of CTA in the early workup of patients in whom CAD is being considered. Current published studies of CTA in the management of acute chest pain in the ER are clearly inadequate to determine utility. No comparator strategy was specified in any study, and there was no solid reference standard for diagnosis. Clinical trials may be necessary to demonstrate utility in this setting.
  CTA as a substitute for coronary angiography in the diagnosis of coronary artery stenosis **does not meet the TEC criteria.** CTA in the evaluation of acute chest pain in the emergency room also does not meet the TEC criteria.

  Based on Blue Cross Blue Shield Association national policy, computed tomographic angiography for coronary artery evaluation is considered **investigational.**
  http://www.bcbs.com/tec/vol21/21_05.html

- *NLM, Medline, Cochrane Library, EMBASE, other:*

  - Hoffmann MH, Shi H, Schmitz BL, Schmid FT, Lieberknecht M, Schulze R, Ludwig B, Kroschel U, Jahnke N, Haerer W, Brambs HJ, Aschoff AJ. *Noninvasive coronary angiography with multislice computed tomography.* JAMA. 2005 May 25;293(20):2471-8.

  Hoffman et al had an objective to assess the accuracy and robustness of MSCT vs the criterion standard of invasive coronary angiography for detection of obstructive coronary artery disease. In a prospective, single center study conducted, 103 consecutive patients underwent both invasive coronary angiography and MSCT using a scanner with 16 detector rows. Blinded results for both modalities compared using the patient as the primary unit of analysis, with supplementary segment- and vessel-based analyses. One thousand three hundred eighty-four segments (> or =1.5 mm diameter) were identified by invasive coronary angiography; nondiagnostic image quality of MSCT was identified for only 88 (6.4%) of these segments, mainly due to faster heart rates. Compared with invasive coronary angiography for detection of significant lesions (>50% stenosis), segment-based sensitivity, specificity, and positive and negative predictive values of MSCT were 95%, 98%, 87%, and 99%, respectively. Quantitative comparison of MSCT and invasive coronary angiography showed good correlation (r = 0.87, P<.001), with MSCT systematically measuring greater-percentage stenoses (bias, +12%). Threshold optimization allowed either detection of these patients with 100% sensitivity at a reasonable false-positive rate (specificity, 76.5%; MSCT stenosis, >66%) or optimization of both the sensitivity and specificity (>90%; MSCT stenosis, >76%). The conclusion was that **Multislice computed tomography provides high accuracy** for noninvasive detection of suspected obstructive coronary artery disease. This promising technology has potential to **complement diagnostic invasive coronary angiography in routine clinical care.**

  - Hacker M, Jakobs T, Matthiesen F, Vollmar C, Nikolaou K, Becker C, Knez A, Pfluger T, Reiser M, Hahn K, Tiling R. *Comparison of spiral multidetector CT angiography and myocardial perfusion imaging in the noninvasive detection of functionally relevant coronary artery lesions: first clinical experiences.* J Nucl Med. 2005 Aug;46(8):1294-300.

correlated well with IVUS. A **major limitation is the insufficient ability of CT to exactly quantify the degree of stenosis**.

- *American College of Radiology:* (Oct 2005):
  In the ACR practice guideline for the performance and interpretation of CT angiography (CTA) suggests that CTA is a proven and useful procedure for the detection and characterization of vascular diseases and of vascular anatomy relevant to the treatment of extravascular disorders. CT angiography may be used as the primary modality for detecting disease or as an adjunctive tool for better characterizing known disease or assessing changes in disease state over time. While it is not possible to detect all abnormalities using CT angiography, adherence to the guidelines will maximize the probability of their detection.

- *Report of the American College of Cardiology Foundation.* (2006)
  In the report, it suggests that Computed tomographic angiography, while very promising with regard to the detection of coronary stenoses, definition of "soft plaque," assessment of left ventricular function and congenital coronary anomalies, and evaluation of cardiac structures, has limited data supporting its use for many clinical applications, especially with regard to its role within patient care algorithms. In an effort to respond to the need for the rational use of these newer imaging techniques, cardiac computed tomography (CCT) and cardiac magnetic resonance (CMR) imaging, the American College of Cardiology Foundation, in conjunction with the societies listed on the report, undertook a process to determine the appropriateness of selected indications for the rapidly evolving cardiovascular imaging procedures. The Appropriateness Criteria Project was initiated to support the delivery of quality cardiovascular care and to ensure the effective use of diagnostic imaging tools.

2. *Benchmarks:*
   - *Blue Cross Blue Shield of Mass.*: (Jan 2006) Policy Updates mention "Clarified **non-coverage** for high-speed CT to include contrast-enhanced CT angiography for coronary artery evaluation performed with high-speed CT technology".
     http://www.bluecrossma.com/common/en_US/medical_policies/999.htm

   - *BCBS (TEC):* (Aug 2006) There is no evidence except in the ER regarding the use of CTA in the early workup of patients in whom CAD is being considered. Current published studies of CTA in the management of acute chest pain in the ER are clearly inadequate to determine utility. No comparator strategy was specified in any study, and there was no solid reference standard for diagnosis. Clinical trials may be necessary to demonstrate utility in this setting. CTA as a substitute for coronary angiography in the diagnosis of coronary artery stenosis **does not meet the TEC criteria**. CTA in the evaluation of acute chest pain in the emergency room also does not meet the TEC criteria.

   - *Aetna:* (Jan 2006) Aetna considers cardiac CT angiography **experimental and investigational** for evaluating coronary artery disease, coronary artery bypass grafts, and coronary anomalies; it has not been proven to be as accurate as standard invasive coronary angiography for evaluating the coronary arteries. http://www.aetna.com/cpb/data/CPBA0228.html

   - *Tufts:* No policy found

   - *Cigna:* (Dec 2005) CIGNA HealthCare **does not cover** multidetector-row CTA for the following clinical indications because it is considered experimental, investigational or unproven:
     - cardiac imaging, for coronary artery disease screening or diagnostic evaluation
     - screening in any asymptomatic population

     http://www.cigna.com/health/provider/medical/procedural/coverage_positions/medical/mm_0399_coveragepositioncriteria_computed_tomography_angiography.pdf

6. A physician or qualified non-physician provider must be present during testing.
7. The electon beam tomography (EBT) technology is not covered.
8. The test may be denied on post-pay review as not being medically necessary when it is used for:
a) Coronary artery evaluation of a patient where there is pre-test knowledge of extensive coronary calcification that would diminish the interpretive value
b) Coronary artery evaluation of a patient presenting with an acute myocardial infarction or an acute coronary syndrome.
c) If performed prior to percutaneous revascularization in a patient who has already undergone diagnostic cardiac catheterization.
9. If PTCA follows Coronary CTA, diagnostic cardiac catheterization is considered not medically necessary.

Cost:

Applicable Codes:

HCPCS Codes

S 8093: Computed tomographic angiography, coronary arteries, with contrast material(s)

CPT Codes

0146T: Computed tomographic angiography of coronary arteries (including native and anomalous coronary arteries, coronary bypass grafts), without quantitative evaluation of coronary calcium

0147T: Computed tomographic angiography of coronary arteries (including native and anomalous coronary arteries, coronary bypass grafts), with quantitative evaluation of coronary calcium

0149T: Cardiac structure and morphology and computed tomographic angiography of coronary arteries (including native and anomalous coronary arteries, coronary bypass grafts), with quantitative evaluation of coronary calcium

References/Footnotes:

1) Hayes Medical Technology Directory. *Helical Computed Tomography for Coronary Artery Disease,* February 2000.
2) Hayes Technology Brief. *64-Slice Computed Tomography Angiography (CTA) for Coronary Artery Disease.* August 2005.
3) Blue Cross Blue Shield Association Technology Evaluation Center (TEC). *Electron Beam CT Scan, Ultrafast CT, Cine CT, & High-speed CT for heart disease and screening for lung cancer.* Policy 355, Reviewed Based on National Policy, 01/05
4) Blue Cross Blue Shield Association Technology Evaluation Center (TEC). *Contrast-Enhanced Cardiac Computed Tomographic Angiography* in the Diagnosis of Coronary Artery Stenosis or for Evaluation of Acute Chest Pain, Volume 21, No. 5, August 2006.
5) CMS, Medicare Coverage database. http://www.cms.hhs.gov/mcd/viewncd.asp?ncd_id=220.1&ncd_version=1&basket=ncd%3A220%2E1%3A1%3AComputerized+Tomography
6) CMS, National Heritage Insurance Company. LCD for Multislice or Multidetector Computed Tomographic Angiography of the Heart and Great vessels. March 2006. http://www.medicarenhic.com/ne_prov/lmrp/draft/madraft_multicta1205.htm
7) Food and Drug Administration (FDA) [website]. Center for Devices and Radiological Health (CDRH). 510K datatbase searched with JAK product code. http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm
8) ACR practice guideline for the performance and interpretation of CT angiography (CTA) October 2005. http://www.acr.org/s_acr/bin.asp?CID=546&DID=22486&DOC=FILE.PDF
9) American Society of Nuclear Cardiology. Computed Tomographic Imaging within Nuclear Cardiology Information Statement. November 2004. http://www.asnc.org/yourpractice/computed_tomographic_imaging.pdf

Technology Assessments for Cardiac Catheterization Performed In Other Than A Hospital Setting (CAG-00166N)

Cardiac Catheterization in Freestanding Clinics

Issue

The Centers for Medicare and Medicaid Services (CMS) has discovered a discrepancy in section 35-45 of the Coverage Issues Manual (CIM). The policy states that cardiac catheterization may be covered in a freestanding clinic when the carrier, in consultation with the appropriate Peer Review Organization, determines that the procedure can be performed safely in all respects in the particular facility. The Peer Review Organizations (recently renamed Quality Improvement Organizations) ceased doing reviews of core freestanding, cardiac catheterization facilities in the early 1990s. Since the implementation of CIM 35-45, we are unaware of any emerging evidence that there is a greater risk of adverse events at these freestanding clinics. Therefore, CMS is opening this policy to review the evidence and correct the discrepancy.

National Clearinghouse Guideline for Acute MI

A. **Early Conservative Versus Invasive Strategies**

Class I

1. An early invasive strategy in patients with UA/NSTEMI without serious comorbidity and who have any of the following high-risk indicators (Level of Evidence: A):
   a. Recurrent angina/ischemia at rest or with low-level activities despite intensive anti-ischemic therapy
   b. Elevated troponin T (TnT) or troponin I (TnI)
   c. New or presumably new ST-segment depression

Attachment C

FirstHealth

Charles T. Frock
Chief Executive Officer

July 31, 2007

State Health Coordinating Council, and
Medical Facilities Planning Section
Division of Facility Services
2714 Mail Service Center
Raleigh, North Carolina 27699-2714

I am writing this letter to express support of Scotland Memorial Hospital's request for an adjustment in the need determination for Scotland County in the *Proposed 2008 State Medical Facilities Plan (SMFP)* to identify a need for one unit of shared fixed cardiac catheterization equipment in Scotland County.

As you are aware, we have been Scotland Memorial Hospital's mobile cardiac catheterization service provider since July 2002. We have been proud to work with the hospital and their cardiologists to help grow their volume from 62 procedures in 2001 to 427 procedures in 2006. The increase in cath procedures at Scotland Memorial Hospital has not negatively impacted our program. As a matter of fact, the hospital, our medical staff, and the patients have benefited greatly from a more coordinated working relationship between the two institutions.

Please accept this letter as our support of Scotland Memorial's request for an adjustment in the need determination in the *Proposed 2008 SMFP* for one unit of shared fixed cardiac catheterization equipment in Scotland County. If approved, we will work together to help establish a shared fixed cardiac catheterization service in Scotland County.

If you have any questions or require any additional information, please do not hesitate to contact me at 910-715-1442.

Sincerely,

Charles T. Frock
Chief Executive Officer

The CCTA Data Registry suggests that CCTA reduces cost to the healthcare system (Exhibit A). Substitutions for either catheter angiography or SPECT imaging generate savings. The findings from our registry suggest that the average cost, on a per patient basis for diagnostic imaging, was reduced by $481 following the implementation of CCTA.

With 64-slice CCTA, a transition occurred within the cardiovascular diagnostic imaging arena. Both clinical performance and the number of applications were enhanced when combining 64-slice CCTA with several key components:

1. CCTA trained technologists
2. Detailed patient selection protocols
3. Efficacious scanning protocols
4. Highest concentration of contrast to allow visualization of smaller vessels
5. Physician leaders that meet or exceed the ACR/ACC competency statements
6. Key elements included uniformly within interpretations

Coronary Computed Tomography Angiography has emerged as an important non-invasive diagnostic technique for coronary disease as well as other cardiac problems. It is anticipated CCTA will dramatically alter the diagnostic paradigm for coronary artery disease.

EXHIBIT A:
Clinical and Economic Impact of CCTA: Preliminary Results of the CCTA Data Registry

A. Objectives

Using data from the CCTA Data Registry (Cardiovascular Innovations, LLC), we analyzed the impact of CCTA both clinically and economically.

B. Methods

64-slice CCTA data from 26 practices/hospitals (15,710 cases) across the United States participating in the CCTA Data Registry were reviewed for this analysis.

This economic analysis of the impact of CCTA services on reimbursements, along with a critical review of the clinical appropriateness and clinical impact of CCTA was conducted from November, 2005 through November, 2006. Data collection was performed in a similar manner at all institutions.

Data from every CCTA patient from each practice were included in the analysis. Data providing the clinical indications for CCTA, diagnostic imaging procedural volumes, global allowable reimbursement rates, normal catheterization rates, and patient volumes were obtained from the

of CCTA services, 15,710 CCTA procedures were added. Diagnostic catheter angiography volumes decreased (5%) in the twelve months following CCTA implementation despite an average 10% growth rate within the overall patient volumes in each practice. In addition, a marked reduction in nuclear perfusion studies (n = 11,470, 8%) occurred in the 12 month period following the introduction of CCTA into clinical practice. Despite the 10% overall patient growth rate during the measured time, nuclear perfusion volumes declined by 8% contradictory to what would have been predicted.

Normal Result Catheterization Rates
Normal Results Total Caths %
pre-CCTA 10,703 46,532 23%
post-CCTA 7,938 44,111 18%

A good barometer of the impact of a CCTA program is the percentage of patients having â?normallâ? or â?essentially normallâ? diagnostic catheter angiographies. A successful CCTA program should ideally reroute those moderate risk patients to the CCTA lab in lieu of traditional angiography, thereby reducing the number of normal results stemming from the diagnostic catheterization lab. Our results indicate a decline in normal results among catheterization patients. The observed 5% decline following CCTA implementation suggests that CCTA is being used appropriately, and that CCTA is adding clinical value to the overall diagnostic imaging program.

Clinical Indications for CCTA
Among states and payors that currently allow CCTA reimbursement, the most common clinical indications include; known coronary artery disease, prior revascularization, chest or pre-cordial pain, shortness of breath, valve disorders, and angina. These indications allow the cardiovascular practitioner to non-invasively image the intermediate risk patient as well as monitor disease progression in the patient with known disease. Furthermore, these indications limit the scope of patients that are allowable for CCTA, thereby preventing the utilization of CCTA as a screening technique.
The clinical indications used by practitioners included in this analysis are presented below in a tabular format. Clinical indication data from these practices for 2005-2006 clearly demonstrate that the physicians are employing appropriate clinical judgment when ordering CCTA studies. Furthermore, the clinical indication data suggest that these practices apply a very narrowly defined scope of indications for which CCTA is being ordered (96% of CCTA studies were ordered

Diagnostic Pathway 2: The patient proceeding from nuclear perfusion testing to CCTA will have had either an abnormal or equivocal nuclear study. Diagnostic Pathway 2 is a true substitution of CCTA for Cath. In the absence of a CCTA program the patient with an abnormal or equivocal nuclear study would instead progress to catheterization.
Multiply every Diagnostic Pathway 2 patient by the difference between the global allowable for a Cath ($2800) and the $1000 allowable for a CCTA.
Diagnostic Pathway 3: In Diagnostic Pathway 3, the symptomatic patient enters the diagnostic imaging pathway at CCTA as a substitution for a nuclear perfusion study. This pathway like Diagnostic Pathway 2 is a true substitution of imaging modalities with CCTA providing the less invasive and less expensive entry point.
Multiply every Diagnostic Pathway 3 patient by the difference between the global allowable for a nuclear perfusion study ($1311) and the $1000 allowable for a CCTA.
Diagnostic Pathway 4: The patients who enter the diagnostic imaging pathway with CCTA and then progress to a nuclear perfusion study comprise Diagnostic Pathway 4. A fraction of patients with an abnormal CCTA will require a perfusion study to evaluate the hemodynamic impact of the lesion (s). This pathway does not add or subtract a test, as this is a clinically appropriate pathway. In the absence of a CCTA program the practitioner would start at nuclear perfusion and potentially find a functional deficit that requires cath for anatomic evaluation.
Diagnostic Pathway 5: These patients first undergo a diagnostic catheter angiography and then progress to CCTA. This could occur for a variety of reasons, but the substitution is a CCTA for a nuclear perfusion study. In these instances the physician did not obtain the data needed from diagnostic catheterization alone and in the absence of a CCTA program a nuclear perfusion study would have been ordered.
Multiply every Diagnostic Pathway 5 patient by the difference between the global allowable for a nuclear perfusion study ($1311) and the $1000 allowable for a CCTA.
Layered Tests: These patients have all three diagnostic tests, which may occur for a variety of reasons. Since this pathway includes all 3 imaging modalities, and this is a major concern of the payors, we will multiply the number of patients on this pathway by the mean global reimbursement for CCTA ($1000).
The Diagnostic Pathways utilized at these practices among the 15,710 CCTA patients are displayed below in tabular form.

and that CCTA adds clinical value to patient management while affecting a cost savings for the health care system. This conclusion is supported by the narrowly defined and appropriate clinical indications followed by these practices which are supported by the established Clinical Appropriateness Criteria. A decline in diagnostic procedural volumes for stress perfusion imaging and diagnostic catheter angiography following implementation of CCTA further supports this observation.
The economic analysis in this study predicts significant savings to the health care system following the implementation of a CCTA program. Despite the increase in the number of patients served at the institutions involved in this analysis, a decline in nuclear perfusion studies and invasive angiographic procedures occurred. The reduction among these procedures resulted in savings to the healthcare system of over seven million dollars within this cohort of patients. The savings on a per patient basis for diagnostic imaging was $481. Directing patient evaluation to CCTA provides a safer, less invasive, more cost effective and potentially more accurate strategy for diagnosis of coronary disease.

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Technology and Equipment Committee Meeting

August 29, 2007

CARDIAC CATHETERIZATION MATERIAL

Material Related to

Comments: Scotland Memorial

Supplemental Information for Petitions filed by Halifax Regional Medical Center and Scotland Memorial Hospital for Special Need Determination for Shared Fixed Cardiac Catheterization Laboratories in Halifax and Scotland Counties.

Petitioner 1:
Halifax Regional Medical Center
250 Smith Church Road
Roanoke Rapids, NC 27870

Petitioner 2:
Scotland Memorial Hospital
500 Lauchwood Drive
Laurinburg, NC 28352

Contact 1:
William Mahone, V
President
Halifax Regional Medical Center
250 Smith Church Road
Roanoke Rapids, NC 27870
(252) 535-8011

Contact 2:
Gregory C. Wood
President and CEO
Scotland Memorial Hospital
500 Lauchwood Drive
Laurinburg, NC 28352
Ph: 910-291-7501

The following information provided by Phillips shows the contents of a "cardiac package" that can be acquired and installed on an angiography laboratory to render it capable of producing high quality cardiac catheterization. Note that the angiography laboratory camera is designed with a wide field needed to view a peripheral vascular bed. The cardiac package provides hardware and software to narrow the camera aperture and increase the shutter speed to handle the requirements of a beating heart. The estimated cost of a package like this is approximately $200,000. Thus, the adaptation costs of a shared lab make this a highly cost effective solution for a rural area.

By contrast, typically a cardiac catheterization laboratory has only the narrow aperture camera. The current MedCath laboratories are narrow aperture labs.

1 **NNAE085 **Allura Xper FD20 Card Sys** 1

The Allura Xper FD20 Cardiac single plane cardiovascular system is comprised of a ceiling mounted stand and digital imaging X-ray system for cardiovascular diagnostic and interventional procedures

The Allura Xper FD20 system uses an integrated single-host concept. The system is comprised of five functional building blocks: Geometry, X-ray Generation, User Interface, Image Detection, and Viewing. Each functional building block is explained in further detail.

Xres Cardiac (NCVA664)

- Xres Cardiac enhances sharpness, contrast, and reduces noise in fluoroscopy and exposure runs for cardiac studies

13	**NCVA675	**3D Roadmapping**	1	**$52,260.00**	**$52,260.00**

This extends the capabilities of the integrated 3D product by providing a sustainable 3D roadmap to support interventional procedures.

The 3D Roadmap option matches the real-time 2D fluoro images with the 3D reconstruction of the vessel tree. So one can see the advancement of the guide wire, catheter and coils on the 3D volume in real time

The 3D roadmap will remain if one changes the C-arm position, the SID and/or the Field of View of the flat detector The 3D volume will follow automatically the orientation of the C-arc, providing the flexibility to chose the optimal position of the C-arc.

Greensboro PH
7-20-07
Cardiac Cath
Tom

SCOTLAND MEMORIAL HOSPITAL

Comments on Proposed 2008 State Medical Facilities Plan
Greensboro, July 20, 2007

Petitioner:

Scotland Memorial Hospital
500 Lauchwood Drive
Laurinburg, NC 28352
Ph: 910-291-7000

Contact:

Gregory C. Wood, President and CEO
Scotland Memorial Hospital
500 Lauchwood Drive
Laurinburg, NC 28352
Ph: 910-291-7000

Good afternoon, my name is Ruth Glaser. I have served as Vice President of Operations at Scotland Memorial Hospital and been a Scotland County community member since 1997. I am here today to comment on the proposed Methodology and Need Determination for Cardiac Catheterization Equipment in Scotland County. I am specifically here to request that the Plan be amended to include a shared fixed cardiac catheterization laboratory for Scotland County.

Let me first thank the State Health Coordinating Council (SHCC) and the Division of Facilities Services Planning Staff for providing the opportunity today for me to come and comment on the *Proposed 2008 State Medical Facilities Plan*.

Scotland Memorial Hospital is a 97-bed acute care facility in Laurinburg, North Carolina and has recently received State approval for 21 additional beds. We are independent, not for profit, and community owned. As the only hospital in rural Scotland County, Scotland

Memorial is the county's primary provider of inpatient acute care, diagnostic and therapeutic services, and emergency services. Laurinburg and Scotland Memorial Hospital are located on the Southern border of North Carolina and are surrounded by the rural counties of Scotland, Robeson, Richmond and Hoke in North Carolina and Marlboro County, South Carolina. These counties form Scotland Memorial's service area. Heart disease age-adjusted mortality rates in Scotland County are 121 percent of the State average, the percent of its population living below poverty is nearly 50 percent more than the State's and Scotland County's median income is only 74 percent of the State's median income. Averages in the other service area counties mirror Scotland's.

Our service area is rural. While urban residents become accustomed to driving on interstates and beltlines in congested traffic areas, this is not true for elderly people in rural areas. We have patients with third party coverage who refuse to leave Scotland County to get cardiac catheterization recommended by their physicians. Cost of travel is a barrier, access to transportation is a barrier, and access to a driver with time to transport is a barrier.

The State Plan's methodology for calculating need for a unit of shared fixed cardiac catheterization equipment itself is imperfect. The methodology sets a moving target based on the number of 8-hour days of mobile service. With one day of service a week, the target is 240 procedures. We have contracted for mobile cardiac catheterization service for more than fifteen years. As our utilization increases, nearing the 240-procedure threshold, scheduling procedures becomes difficult and our patients and physicians push to increase the number of days of mobile service. When we add an 8-hour day, or add an hour to a day, the target moves up 240 procedures a year for each eight hours a week. Scotland Memorial, in fact, surpassed the 240-procedure threshold in 2003, and was forced to add another day to provide adequate scheduling and good patient care. We ask that you give us a chance to make efficient use of our resources and technology to give residents of our service area access to the care that their insurance will cover.

As we considered the impact of waiting until the Plan shows a need in Scotland County, we realized the delay was not acceptable. Even with a need listed in the 2008 Plan, it will be 2010 before we would get a Certificate of Need approved. We are dealing with a population with advanced cardiac disease that needs adequate access to these services now. Please do not delay our ability to make this resource available 24/7 by yet another year. Our quality systems are in place, our staff is trained, we simply need access to the technology. We currently have 67 active physicians on our medical staff in a wide range of 20 specialties. We have two full-time and one part-time board certified cardiologists. We have experience providing this service with quality outcomes. We also have the appropriate physicians on staff with the required back up in place. Our cardiologists have performed over 1700 cardiac catheterization procedures at Scotland Memorial since 2002. Yet, we are forced to refer out many service area patients to First Health Moore, UNC and Duke each year because mobile cardiac cath service limits our capacity so severely. Making us wait only increases the overhead we pay to a mobile provider and restricts the availability of the service.

Anyone who has worked with a mobile service knows the drawbacks. Trucks break down, equipment is jostled, patient privacy is compromised, and most importantly, the equipment is not there when the patients most need it.

With over 3,000 cardiac catheterizations in our service area every year, it will take only a token 7 percent market share to surpass the 225 procedure threshold required by Administrative Rule 10A NCAC 14C .1603 (d) Performance Standards for shared fixed cardiac cath equipment. A conservative market share of 15 percent will sustain a strong shared fixed cardiac catheterization laboratory with more than double the 225 shared procedure threshold. More importantly, offering a shared fixed lab will permit our medical staff to give our patients the healthcare services they deserve in their home community.

I understand the role of the State Planning process in containing costs and minimizing duplication. It is equally important to consider the second basic plan principle, -

improving access. North Carolina's urban centers: Charlotte, Asheville and Raleigh are growing rapidly and have many more medical resources. We can do a better job of sustained growth in North Carolina if we think about spreading the resources in a way that makes the outlying communities attractive. To support our residents, we need the technology to make our medical support system attractive to physicians, nurses and health-care technologists. Cardiac catheterization rates have been steadily increasing in North Carolina, about 2 percent a year for the past seven years. Permitting us to do a limited number of procedures at Scotland Memorial Hospital will not hurt any of the existing programs. Increases in use rate and population will more than offset any procedures that might remain in Scotland County rather than travel outside.

Failing to request an adjustment in the need determination for Scotland County to include a shared fixed cath lab would be failing to continue our mission of providing our community with high quality, compassionate health care. With only two days of mobile cardiac cath services, we are already compromising the service patients and their family member's desire and deserve – any growth in use rate or population will make it worse.

It is with that goal in mind that we are petitioning the Medical Facilities Planning Section to adjust the need determination in the Proposed 2008 SMFP to identify a need for one shared fixed cardiac catheterization laboratory in Scotland County. We believe based on historical utilization, statistical analysis, physician recruitment, physical space and staffing patterns at Scotland Memorial Hospital that adding a shared fixed lab is the most efficient way to meet the hospital's and our service area's need for cardiac care. The formal petition we will submit includes the data and the analyses used to arrive at this decision.

Our request is made to serve our community appropriately. It is not about expanding our territory, nor are we expanding our competitive efforts. I do not expect other hospitals in our adjoining counties to dispute our request nor are we duplicating their services. In fact, our mobile service provider and the hospital that receives most of the referrals for caths we cannot do, FirstHealth Moore Regional Hospital, is in full support of our

petition. No other viable alternative exists that would not create continued adverse effects on our county's residents.

In conclusion and on behalf of Scotland Memorial Hospital, I first want to thank the SHCC and Planning Staff for their service to our state. This process is still the soundest mechanism for fairly determining health care needs for our great state.

On behalf of our Board, staff, and physicians and more importantly, our service area residents and Scotland Memorial Hospital patients, I want to thank you for the opportunity to make this request today. Failing to grant our request would be unfair to Scotland Memorial service area residents and would fail to promote adequate access to quality health care services for those residents.

F:\Client Projects\Scotland Memorial Hospital\2007 Summer Petition\PublicHearingComments_Greensboro.doc

Raleigh PH
8-1-07
Cardiac Cath

Comments on Proposed 2008 State Medical Facilities Plan
Raleigh, August 1, 2007

Petitioner:

Scotland Memorial Hospital
500 Lauchwood Drive
Laurinburg, NC 28352
Ph: 910-291-7000

Contact:

Gregory C. Wood, President and CEO
Scotland Memorial Hospital
500 Lauchwood Drive
Laurinburg, NC 28352
Ph: 910-291-7000

Good afternoon, my name is Greg Wood. I have served as the President and Chief Executive Officer of Scotland Memorial Hospital and been a Scotland County community member since 1990. I am here today to comment on the proposed Methodology and Need Determination for Cardiac Catheterization Equipment in Scotland County. I am specifically here to request that the Plan be amended to include a shared fixed cardiac catheterization laboratory for Scotland County.

Let me first thank the State Health Coordinating Council (SHCC) and the Division of Facilities Services Planning Staff for providing the opportunity today for me to come and comment on the *Proposed 2008 State Medical Facilities Plan*.

Scotland Memorial Hospital is a 97-bed acute care facility in Laurinburg, North Carolina and has recently received State approval for 21 additional beds. We are independent, not for profit, and community owned. As the only hospital in rural Scotland County, Scotland

to the mobile pad outside the front entrance of the hospital. When the procedure is complete, they are wheeled back through the hallways to recovery.

Continuing to add mobile days of cardiac cath service and waiting until the Plan shows a need in Scotland County will result in an unacceptably long delay in full-time cardiac cath service in Scotland County. Even with a need listed in the 2008 Plan, it will be 2010 before we could begin servicing our community. We are dealing with a population with advanced cardiac disease that needs adequate access to these services now. Please do not delay our ability to make this resource available 24/7 by yet another year. We currently have 67 active physicians on our medical staff in a wide range of 20 specialties. We have two full-time and one part-time board certified cardiologists, with a verbal offer recently extended to a locally born cardiologist finishing his fellowship. We have experience providing this service with quality outcomes. We also have the appropriate physicians on staff with the required back up in place. Our cardiologists have performed over 1,700 caths at Scotland Memorial since 2002 – more than enough to remain proficient. Yet, we are forced to refer out many service area patients to First Health Moore, UNC and Duke each year because mobile cardiac cath service limits our capacity so severely and we do not have a 64-slice CT. Making us wait only increases the overhead we pay to a mobile provider and restricts the availability of the service.

With over 3,000 cardiac catheterizations in our service area every year, it will take only a token 7 percent market share to surpass the 225 procedure threshold required by Administrative Rule 10A NCAC 14C .1603 (d) Performance Standards for shared fixed cardiac cath equipment. A conservative market share of 15 percent will sustain a strong shared fixed cardiac catheterization laboratory with more than double the 225 shared procedure threshold. More importantly, offering a shared fixed lab will permit our medical staff to give our patients the healthcare services they deserve in their home community.

The role of the State Planning process in containing costs and minimizing duplication is an important one. It is equally important to consider the second basic plan principal, -

viable alternative exists that would not create continued adverse effects on our county's residents.

In conclusion, I want to thank the SHCC and Planning Staff for their service to our state. This process is still the soundest mechanism for fairly determining health care needs for our great state.

And, on behalf of our Board, staff, and physicians and more importantly, our service area residents and Scotland Memorial Hospital patients, I want to thank you for the opportunity to make this request today. Failing to grant our request would fail to promote adequate access to quality health care services for those residents.

Thank you.